



early
MEDICAL ABORTION

**A PRACTICAL GUIDE
FOR HEALTHCARE
PROFESSIONALS**

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Editorial

I have had the opportunity to follow from its beginning the slow but successful development of a medical method to terminate early pregnancy.

It started with the identification of prostaglandins and their chemical structure by Professor Sune Bergström and co-workers in 1960, and the development of prostaglandin analogues which strongly stimulated uterine contractility and could, in contrast to primary prostaglandins, be administered by non-invasive routes. Vaginal administration of gemeprost, for example, could effectively terminate early pregnancy. However, the dose needed was high and intense uterine pain and gastro-intestinal side effects were common, limiting treatment acceptance.

The next step towards a medical abortion method was the development of mifepristone by the French scientist Professor Etienne-Emile BAULIEU and co-workers in the early 1980s. Mifepristone is an antiprogesterone, blocking the progesterone receptor. Treatment with mifepristone changes the inactive pregnant uterus to an active organ with regular contractions. In addition mifepristone softens the cervix, facilitating the expulsion of the conceptus. However, it was soon found that mifepristone was not sufficiently effective to be clinically useful for medical abortion.

The significant breakthrough was our finding that treatment with mifepristone also increased the sensitivity of the myometrium to prostaglandin. Following pretreatment with mifepristone, a low dose of prostaglandin analogue was sufficient to induce effective uterine contractions. **With the combined therapy, the success rate was high and, since a low dose of prostaglandin could be used, the side-effects were kept at an acceptable level.**

The introduction of routine medical abortion has been slow. One reason has been the negative attitude to an “abortion pill” on the part of various groups in society, based on the fear that a simple and effective abortion method would increase the abortion rate. This has not happened and is unlikely to be the result. With medical abortion it is the woman herself who takes the responsibility when she takes the

drugs, and experiences the uterine contractions and the expulsion of the conceptus, in contrast to the alternative (vacuum aspiration) where it is the doctor who performs the abortion. Another reason is the attitude of the doctor. It may seem difficult to understand that women often prefer medical abortion, despite the fact that the alternative is a short, 10-minute surgical procedure with very little discomfort: it is, however, the case. Once medical abortion has been introduced in a country, its acceptability for women always increases. It is possible that the similarity to miscarriage, which is a natural process, makes medical abortion more attractive than the surgical procedure.

Another important aspect of medical abortion during early pregnancy is the simplicity of the treatment. The similarities with miscarriage mean that the clinical events are well known, not only to the doctor but also to many middle-level professionals and to the woman herself. In Sweden, midwives have, with back-up from a doctor, taken over most of the management of medical abortion. Also, in countries with limited medical facilities, the use of trained midwives or nurses in abortion care can increase the availability of abortion services and decrease the risk of unsafe abortion.

Although medical abortion is a simple treatment, **detailed knowledge of all aspects is essential for safe outcome. This clinical guide, prepared by very skilled and experienced scientists in the field, gives all the information needed to perform a safe medical abortion during early pregnancy.**

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The objective of this chapter is to give an overview of medical abortion in Europe, highlighting the lack of norms and, in those countries where abortion is legal, the discrepancies and restrictions in abortion access and in the use of medical abortion.

HOW IS ABORTION REGULATED IN EUROPE?

The legal situation regarding abortion varies considerably between European countries^a.

Few countries in Europe give women unrestricted access. Most require some conditions to be fulfilled:

- Waiting periods of various length,
- Obligatory counselling,
- Signature of two doctors,
- Written statement by the woman that she is in distress...

In practice, these restrictions do not prevent women from getting abortion on request but may result in an unsafe abortion or in delaying the abortion procedure.

European countries where abortion is in practice not accessible on request in the first trimester are the following:

- Andorra,
- Ireland,
- Liechtenstein,
- Malta,
- Monaco
- Poland,

and parts of the United Kingdom (Northern Ireland, Isle of Man) and of Denmark (Faroe Islands).



Mirella PARACHINI: “In Italy, the law does not allow abortion on request. However, it provides such broad grounds on which abortion is permitted that it has been interpreted by some as allowing abortion on request. In addition, it is the woman herself who attests that she is in one of the situations described by the law and the primary role of the physician is to certify the existence of a pregnancy”.

^a <http://www.un.org/esa/population/publications/abortion/profiles.htm>

Where abortion is legal on request in Europe, the upper time limit ranges between 10 and 24 weeks of amenorrhea (Fig.1). In addition, all countries have legal provisions for later abortion in cases of medical indication for the woman or the foetus.

Fig.1 Legal time limit for performing abortion by European country (in weeks of amenorrhea).



* No fixed upper limit but defined by "potential to survive" (22 weeks in practice).

† 90 days (i.e., 12 weeks + 6 days)

The vast majority of women with an unwanted pregnancy want to terminate it as soon as possible. The gestational age at abortion is independent of the upper gestational age and mainly reflects women's difficulty in gaining access to abortion in their country. The proportion of women in Europe having an abortion in the first 9 weeks of pregnancy is shown in Tab.1.

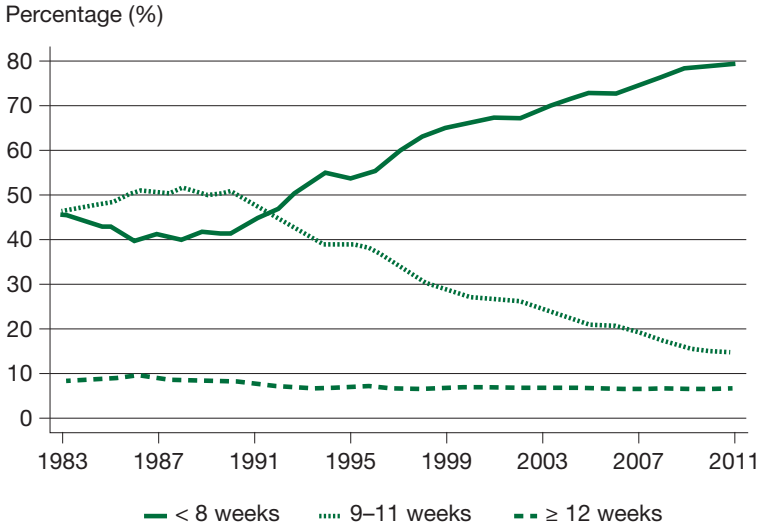
Tab.1 Percentage of abortions before the 9th week of amenorrhea in certain European countries^a

Country	(legal limit)	Percentage of abortions before Week 9 (year)
Finland	(12 weeks)	71% (2010)
Germany	(14 weeks)	73% (2010)
Norway	(12 weeks)	73% (2010)
England & Wales	(24 weeks)	67% (2010)
Netherlands	(22 weeks)	68% (2009)
Sweden	(22 weeks)	80% (2011)

^a *National statistics.*

In recent years, there has been a significant trend in most countries for abortions to be performed earlier, as shown, for example, in Sweden (Fig.2).

Fig.2 Impact of the introduction of medical abortion on gestational age at abortion in Sweden^a



^a Statistics of Sweden, Induced abortions [in Swedish]
(<http://www.socialstyrelsen.se/publikationer2012/2012-5-7>).

MEDICAL ABORTION

In the early 1980s, Etienne-Emile BAULIEU and colleagues, from the French national institute INSERM (Institut National de la Santé et de la Recherche) and the pharmaceutical company Roussel-Uclaf, developed mifepristone (initially known as RU-486). For medical abortion, mifepristone used alone has a maximal effectiveness of 80%, which is insufficient for routine clinical use. The final breakthrough came with the discovery by Marc BYGDEMAN, a leading gynaecologist at the Karolinska Hospital in Stockholm, that mifepristone increased the sensitivity of the pregnant uterus to prostaglandins and that combined treatment significantly increased efficacy. This led to the development of the currently used combined treatment.

In Europe, medical abortion with mifepristone and prostaglandin was first approved in 1988 in France (originally only up to 7 weeks of amenorrhoea), followed by approvals in 1991 in the United Kingdom and in 1992 in Sweden (up to 9 weeks of amenorrhoea). However, it was not until 1999 that medical abortion with mifepristone and prostaglandin was approved in several other European countries (Tab.2).

Tab.2 List of mifepristone approval^a

1988 China France	1999 Austria Belgium Denmark Finland Germany Greece Iceland Israel Luxembourg Netherlands Spain Switzerland	2000 Norway Taiwan Tunisia US 2001 New Zealand South Africa Ukraine 2002 Belarus Georgia India Latvia Russia Serbia Vietnam	2003 Estonia 2004 Guyana Moldova 2005 Albania Hungary Mongolia Uzbekistan 2006 Kazakhstan 2007 Armenia Kyrgyzstan Portugal Tajikistan	2008 Romania Nepal 2009 Italy Cambodia 2010 Zambia 2011 Ghana Mexico Mozambique
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^a List of mifepristone approval. 2011.
(<http://gynuity.org/resources/read/llist-of-mifepristone-approval-en/>).



In 2005, the World Health Organisation (WHO) included the combination of mifepristone and misoprostol for use in medical abortion in its Essential Medicine List.^a

Today, women in most European countries have access to the drugs used in early medical abortion:

- **Mifepristone** (Mifegyne[®]) is authorised in 19 European countries (European Union 27 countries + Norway and Switzerland) for use in medical abortion (Tab.2).
According to the distributor Exelgyn (Paris), more than 3.5 million women have so far been treated with mifepristone in Europe since it was first introduced in 1988.
- **Misoprostol**, an E1 prostaglandin, marketed as Cytotec[®], is registered for use to prevent gastric ulcers in most European countries. It is used for abortion in association with mifepristone.



Gemeprost, another E1 prostaglandin, was formerly used in medical abortion. However, it has been replaced by misoprostol because the latter has fewer side effects, is easier to dose, can be stored at room temperature, and is significantly cheaper.

In European countries, up to 90% or more of women choose medical abortion when available. Medical abortion is currently^b:

- The commonest method of abortion in Scandinavian countries (> 90%), Portugal (65%), Spain (63%) and Switzerland (62%),
- Commonly used in France (54%) and the United Kingdom (Northern Ireland excl., 53%),
- Uncommon in the Netherlands (20%), Belgium (17%) and Germany (15%), and
- Rarely used in Italy (4%).

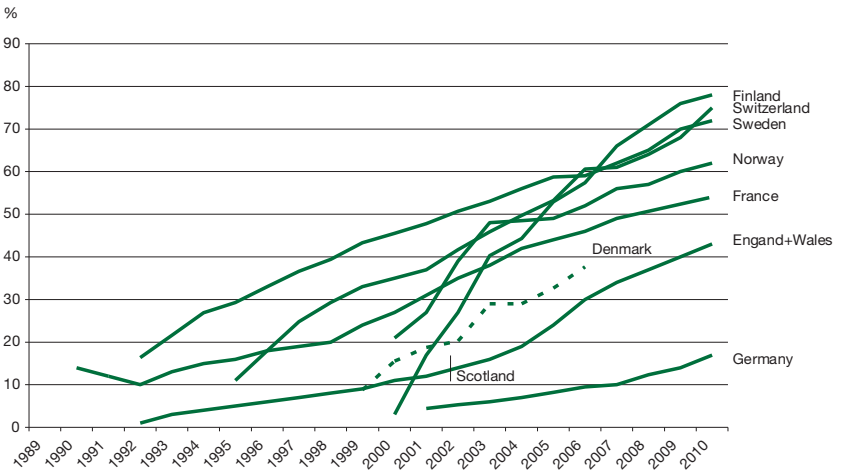
^a Gibson L. WHO puts abortifacients on its essential drug list. *BMJ*. 2005;331(7508):68.

^b Latest official national statistics for: Belgium, France, Germany, Portugal, Spain, Switzerland and the UK. Latest product manager estimates for: Italy, the Netherlands and Scandinavia.

Introduction of medical abortion has been slow in most European countries, **although it is the preferred method of many women if they have the choice^a**.

The proportion of medical abortions is increasing in most European countries (Fig.3).

Fig.3 Percentage of medical abortions from 1989 to 2010^b



^a Moreau C, et al. Medical vs. surgical abortion: the importance of women's choice *Contraception* 2011;84(3):224-9.

^b National statistics.

HOW DOES MEDICAL ABORTION WORK? HOW DO THE TWO MEDICATIONS WORK?

Abortion can be performed with either mifepristone or a prostaglandin alone, but single drug treatment has lower efficacy and a high rate of side effects. The combination of mifepristone and a prostaglandin (commonly misoprostol) has a synergistic effect which allows a lower dose to be used, reduces side effects and increases efficacy.

The combined action of mifepristone and prostaglandin on the decidua and cervix results in detachment and expulsion of the pregnancy, which is very similar to a spontaneous miscarriage due to corpus luteum insufficiency.



Mifepristone and misoprostol act synergistically.

From a clinical point of view, spontaneous and medically induced abortions are exactly the same process.

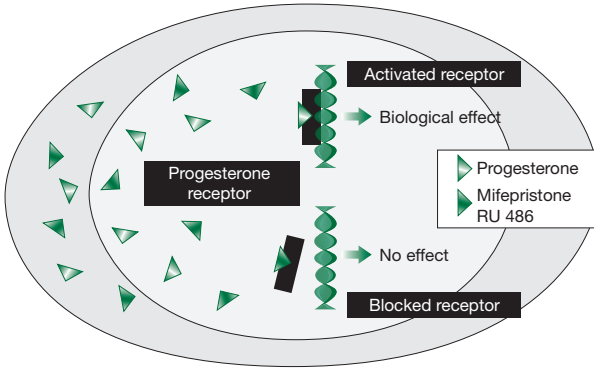
MIFEPRISTONE

Mifepristone is a synthetic hormone, which competitively blocks the progesterone receptors (Fig.4).

Mifepristone has a higher binding affinity to the progesterone-receptor than progesterone. This leads to a competitive blockage of the progesterone receptors by mifepristone. This blockage is fully reversible^{a,b}.

^a Moguilewsky M, Philibert D. Biochemical profile of RU 486. In: Baulieu EE, Segal SJ, editors. *The antiprogesterin steroid RU 486 and human fertility control*. New York: Plenum Press 1985:87-97.

^b Lähteenmäki P, et al. Pharmacokinetics and metabolism of RU 486. *J Steroid Biochem* 1987;27:859-63.

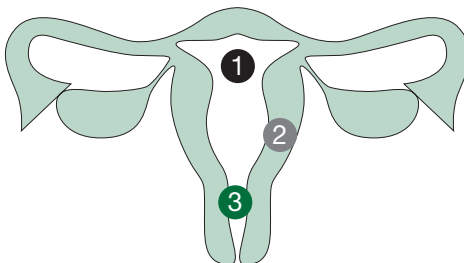
Fig.4 Mifepristone's action in the cell

Progesterone binds to its receptors, triggering DNA transcription and resulting in protein synthesis.
Mifepristone (RU 486) preferentially binds to progesterone receptors, thereby blocking the effects of the progesterone.

At tissue level, mifepristone increases the contractility of the uterus and sensitises the myometrium to prostaglandin. The effect begins 12-24 hours after mifepristone administration and is maximal at 36-48 hours. **Mifepristone also causes the cervix to soften and ripen** and results in a release of endogenous prostaglandins from the decidua (Fig.5).

Fig.5 Mifepristone's action at tissue level

- 1 Detachment of the gestational sac
- 2 Prostaglandin action sensitisation
- 3 Opening and ripening of the cervix



MISOPROSTOL

Misoprostol is a prostaglandin E1 analogue. It induces contractions of the uterus and expulsion of the pregnancy.

Where approved in Europe, misoprostol is licensed as **tablets for oral use**. However, misoprostol is recommended in clinical guidelines and widely used in practice in early medical abortion:

- Via oral route* in pregnancy ≤ 7 weeks of amenorrhea,
- Via other routes (vaginal, sublingual, or buccal)* in pregnancy ≤ 9 weeks of amenorrhea. However, these non-oral routes are not included in approved labels.

The peak plasma level of the active metabolite (misoprostol acid) occurs after less than 30 minutes when administered orally. Absorption after vaginal administration is slower and more variable: peak plasma level is expected at 80 minutes. The plasma elimination half-life of misoprostol acid is 20-40 minutes.



Mifepristone is effective throughout pregnancy. There is thus no upper gestational limit to when medical abortion is effective, but there are specific protocols according to gestational age. **The present practical guide, however, focuses on early medical abortion: i.e., for pregnancies ≤ 9 weeks of amenorrhea.**

* Oral: tablets are swallowed immediately; Vaginal: tablets are placed in the vagina; Sublingual: tablets are placed under the tongue and swallowed after 30 minutes; Buccal: tablets are placed between the cheek and gums and swallowed after 30 minutes.

WHAT IS THE SUCCESS RATE OF MEDICAL ABORTION?

In clinical trials, according to gestational age, the time-interval between mifepristone and prostaglandin administration, the type of prostaglandin used, and the prostaglandin administration route, success rates are between 95% and 98%. Failures occur in 1.3% to 7.5% of cases, including 0 to 1.5% ongoing pregnancies, 1.3% to 4.6% incomplete abortion, and 0 to 1.4% excessive bleeding/haemorrhage.

The following factors affect success rates:

- **Gestational age of pregnancy**
Medical abortion is less effective as gestational age increases. More contractions are needed, thus more prostaglandin needs to be given. Beyond 24 weeks of amenorrhea, the dose needs to be reduced.
- **Mifepristone-prostaglandin regimen**
Regimens vary in terms of dose, timing and administration route.
- **Healthcare professional**
Inexperienced clinicians may have lower levels of success with medical abortion as they tend to intervene surgically at early stages of the process (e.g., in the mistaken belief that termination is not complete). **Surgical evacuation of the uterus after a medical abortion is only indicated if there is a clinical indication such as heavy or prolonged bleeding, ongoing pregnancy and/or if the woman wishes intervention** (for further details, please see “Post-abortion care”, p. 77).
- **Visit schedule**
Many women want to know as soon as possible if the abortion has been complete, and an early follow-up consultation may increase satisfaction. On the other hand, at early follow-up human chorionic gonadotropin (hCG) levels are still high and the uterine cavity may contain more blood, which is sometimes misdiagnosed by inexperienced professionals as incomplete abortion, possibly leading to unnecessary surgery (for further details, please see “Post-abortion care”, p. 77).

WHAT ARE THE DIFFERENT STEPS IN EARLY MEDICAL ABORTION?

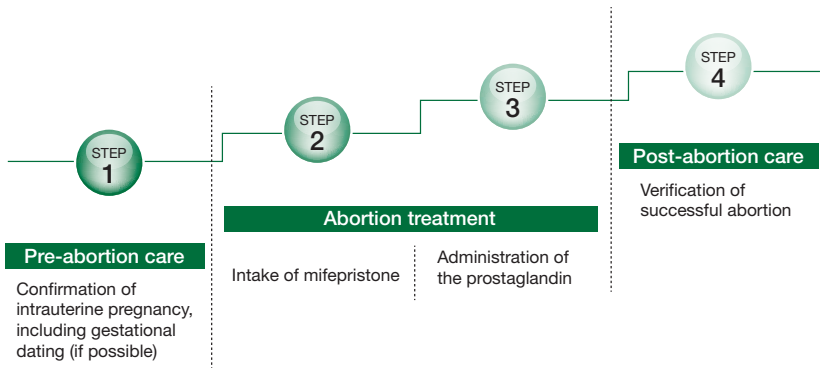
Treatment regimen details vary from one country to another and according to the healthcare professional's experience and national guidelines. For further protocols and details, please see: "What are recommended protocols in early pregnancy?", p. 63.



Each professional should first consult the legal product information applied in his/her country.

Treatment always follows 4 steps (Fig.6)

Fig.6 Medical abortion: a 4-step method



Some of the treatment steps can be done at home, depending on the local situation and national legal regulations. The number of visits therefore ranges between 1 and 4.

CONCLUSION

1. The law on abortion and the administrative regulations vary considerably from one European country to another. Nevertheless, **abortion in the first trimester is accessible on request in most European countries.**
2. Medical abortion was introduced in Europe in 1988. Since this date, it has been increasingly used.
3. **Early medical abortion (≤ 9 weeks of amenorrhea) with mifepristone and a prostaglandin (commonly misoprostol) has been shown to be a highly effective and safe method. It is the preferred method for most women, when they have a free choice. The procedure is very similar to miscarriage.**
4. **Early medical abortion is always a 4-step method:**
 - Confirmation of intrauterine pregnancy
 - Intake of mifepristone
 - Intake of the prostaglandin
 - Verification of successful abortion.
5. **The details of the treatment regimen used in early medical abortion and the protocol followed are variable.** They depend on gestational age, country and the healthcare professional.

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The objective of this chapter is to improve the means of:

- *Delivering information in a confidential, respectful and non-judgemental manner*
- *Describing the different methods of abortion*
- *Describing the advantages and disadvantages of medical abortion*
- *Addressing special issues encountered by women during and just after medical abortion*
- *Delivering information on future contraception.*

WHAT IS COUNSELLING?

The aims of abortion counselling are:

- To help the woman to understand her situation, her options, to come to a self-determined clear decision and to implement her decision,
- To assist her in controlling her future fertility.

Counselling must be able to offer active listening to what the woman has to say and practical information about abortion methods and contraception.

Counselling is probably the most variable step of medical abortion. Depending on the country, it can be performed by a doctor, a midwife, a social worker or a trained counsellor. It can be voluntary or made mandatory by law. It can take place either in the institution where the abortion is to be carried out or in another place.



Healthcare professionals should refer to their national law and/ or local regulations about counselling.

The following chapter focuses on information on abortion (surgical or medical abortion) and future contraception that must be provided by all healthcare professionals to all women who have taken the decision to terminate their pregnancy. **Information should be accurate, impartial and easy to understand.**

Before starting the treatment, the healthcare professional may ask the woman to sign an informed consent form or information form. Examples of templates of an information card and informed consent form for medical abortion are presented in Fig.7 and Fig.8.

Fig.7 Example of template of an information card for medical abortion

Information on Early Medical Abortion

You have decided to terminate your pregnancy medically.

The medical method is carried out in 3 steps and consists of taking 2 drugs:

- Mifepristone (Mifegyne[®])
- And **36 to 48 h later:** prostaglandin (misoprostol):

Mifepristone and misoprostol work together to induce a miscarriage.
Mifepristone interrupts the pregnancy by blocking the hormone needed to maintain the pregnancy (progesterone).
The prostaglandin induces contractions and expulsion of the pregnancy.

THE PROCESS

1. Mifepristone tablets (Mifegyne[®]) taken on at

What can occur after mifepristone (Mifegyne[®]) intake?

- You will most probably not feel any difference until you take the second drug, the prostaglandin.
- In most cases, you can perform your usual activities.
- If you vomit within 1,5 hours following drug intake, contact your physician in order to determine whether another drug dose is necessary.
- On the evening of the following day, some women may experience period-like bleeding, feel tired and have some pain. On rare occasions, there is heavy bleeding with blood clots and cramping.
- It is possible to expel the pregnancy at this stage (happens in 3% of the cases).

Bleeding does not indicate that the pregnancy has been terminated, regardless of how heavy it may be. So it is essential to take the prostaglandin 36 to 48 hours later according to approved schedule.

2. Prostaglandin taken onat

What can happen after prostaglandin intake?

- After prostaglandin intake, you should do everything you like to do. If you have the procedure at home, it is preferable to remain comfortable and to have somebody with you.
- The prostaglandin induces uterine contractions and pain similar to or stronger than menstrual pain. Do not hesitate to take the pain killers that were prescribed to you.
- You may experience nausea, vomiting and diarrhoea.
- Expulsion of the pregnancy is associated with bleeding that is often heavier than menstrual bleeding and contains blood clots. The gestational sac is sometimes visible in the form of a gelatinous white ball 1 to 3 centimetres long. Bleeding can happen very quickly after prostaglandin intake, but it may also happen later, sometimes only the next day:
 - In 60% of cases, expulsion will occur within 4 hours of prostaglandin intake.
 - In other cases, expulsion will happen within 24 hours to 72 hours of prostaglandin intake.

Bleeding lasts about 2 weeks and is generally less abundant than during your period.
If you are still bleeding 3 weeks after prostaglandin intake, you should contact your physician.

IF AT ANY TIME you are worried or if the following occurs: fever (lasting longer than 24 hours), pain that persists despite taking analgesics, significant and persistent blood loss (use of more than 2 sanitary pads per hour for 2 hours) or faintness, please contact: **your doctor** **at the** **department** **of the** **hospital at**

① After an abortion, fertility resumes immediately. A pregnancy can occur with your first sexual intercourse after the abortion. It is essential to start contraception immediately. If you choose the contraceptive pill, start the pack on

3. Follow up examination onat

The follow-up examination must take place 1 to 3 weeks after mifepristone (Mifegyne[®]) intake. The physician will verify that the pregnancy has ended (the failure rate for the method is below 5%) and make sure there are no complications. The efficacy of the method is generally verified by ultra sound examination or a pregnancy test in urine or blood (β -hCG).

Fig.8 Example of template of informed consent form for medical abortion

The undersigned..... hereby,

- confirm that it is my free decision to terminate the pregnancy
- will do so according to the law
- state that I am aware that Termination of Pregnancy (ToP) can be performed by medical or surgical method and that I have chosen the medical ToP
- acknowledge having fully read and understood the document given to me
- certify that someone clearly explained the contraindications and the side effects to me.

I am aware that:

- **The procedure of medical abortion consists of taking Mifegyne® tablets.**
- This dose must be followed by **36 to 48 hours later by the administration of a prostaglandin - misoprostol.**
- **The follow-up consultation is essential to verify expulsion of the pregnancy and takes place 1 to 3 weeks after Myfegine® intake**

- I am fully aware this method is highly effective, but not 100%.
Therefore, in the rare event that the treatment is not completely successful:
 - A repeated medical abortion or a surgical procedure may be required to complete the termination.
 - Should I decide to carry my pregnancy to term, I will inform the physician so that I can receive prenatal medical supervision. **Indeed, there is no guarantee as to the risk for the foetus.**

Patient signature	The patient took Mifegyne® tablets. Physician's signature and stamp
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HOW TO RECEIVE WOMEN WHO COME FOR AN ABORTION?

Woman requesting an abortion should be reassured that the consultation is confidential and that the information she provides is available only to other healthcare professionals directly involved in her care.

The woman's personal details must not be shared with anyone else, unless she has expressly given permission to do so, or in certain specific cases regulated by local law (child abuse, domestic violence, etc.) and special attention has to be given to the needs of adolescents regarding appropriate protection of confidentiality.

Ideally, the reception area, toilets and examination rooms should be separate from those provided for women coming to the same facility for antenatal care and delivery.



Mirella PARACHINI: "Conversations are best held with the woman sitting up rather than lying down, and with the healthcare professional seated at the same level as the woman. This corresponds to an attitude of respect and support and can help ease anxiety."

There is no evidence of a causative association between abortion and mental health problems^{a,b}. However, it can be helpful for the woman to hear during counselling that:

- To feel upset in such a situation is normal.
- Many kinds of experience can be traumatic (e.g., divorce, job loss).
- Approximately a third or more of women of reproductive age have had or will have an abortion (which is likely to include someone that she knows).
- On TV and in magazines, abortion is often dramatized as a political issue that people have to take sides on: it is quite a different matter what real women actually experience.
- A lot of women think that choosing an abortion makes it seem like they don't care about children; but in reality it often means that they care so much about children that they want to be sure they have them only when they can take the responsibility and provide for all their needs.
- Abortion confirms current fertility of both partners and has no effect on future fertility^c.
- Abortion does not increase the risk of breast cancer^{d,e}.

^a Major B, et al. Abortion and mental health. Evaluating the evidence. *Am Psychol* 2009;64(9):863–90.

^b Munk-Olsen T, et al. Induced first-trimester abortion and risk of mental disorder. *N Engl J Med* 2011;364:332-9.

^c Rowlands S. Misinformation on abortion. *Eur J Contracept Reprod Health Care* 2011;16(4):233-40.

^d Committee on Gynecologic Practice. ACOG Committee Opinion No. 434: induced abortion and breast cancer risk. *Obstet Gynecol* 2009;113(6):1417-8.

^e Melbye M, et al. Induced abortion and the risk of breast cancer. *N Engl J Med* 1977;336(2):81-5.

HOW TO HELP THE WOMEN TO CHOOSE BETWEEN THE TWO ABORTION METHODS?

Both methods are effective and safe for abortion within the first trimester of pregnancy:

- Vacuum aspiration (manual or electrical) under anaesthesia (local or general).
- Mifepristone followed by prostaglandin (commonly misoprostol).

For each method, women must be given information on:

- What will be done during and after the procedure.
- What effects and side effects they are likely to experience (e.g., menstrual-like cramps, pain and bleeding).
- How long the procedure will take.
- What kinds of pain management can be made available.
- What risks and complications are associated with the method.
- Follow-up care.
- Start/initiation of contraception or switch to more effective or adapted method of contraception.



Christian FIALA: “The following website contains detailed information about abortion in many languages: www.gynmed.org. I recommend it for women with an unwanted pregnancy.”

WHAT INFORMATION SHOULD BE GIVEN ABOUT SURGICAL ABORTION?

Vacuum aspiration involves evacuating the contents of the uterus through a plastic cannula connected to a vacuum source.

The plastic cannula is inserted into the uterus with or without prior dilation by mechanical dilators, alone or in combination with prostaglandin. The size of the cannula varies according to gestational age. Electrical vacuum aspiration uses an electrical vacuum pump; in manual vacuum aspiration, a vacuum is created using a hand-held 60 ml plastic syringe.

The procedure usually takes place in an operating theatre or outpatient clinic room. It takes between 3 and 10 minutes to complete.

The procedure can be performed on an outpatient basis, using local or general anaesthesia. The woman should be given the choice between local or general anaesthesia.

After the procedure under local anaesthesia, most women feel well enough to leave the healthcare facility after about 30 minutes' observation in a recovery room. Longer recovery periods are generally needed when sedation or general anaesthesia has been used.



If available, an ultrasound scan should be taken immediately after the aspiration to check that the uterine cavity has been emptied.

A follow-up visit is not needed if the evacuation of the uterus has been confirmed during the abortion procedure.

The method is very effective. Electrical and manual vacuum techniques are equally good, **with complete abortion rates ranging between 95% and 100%.**

The vacuum aspiration method is a very safe procedure when performed in a safe environment by a skilled professional in a well equipped facility.

Common side-effects can be: abdominal cramping, pain and menstrual-like bleeding.

Complications (pelvic infection and excessive bleeding) are rare. The following other complications are very rare: cervical injury, incomplete evacuation, perforation of the uterus, anaesthesia-related complications, and ongoing pregnancy.

When approved, all women should be offered presurgical priming of the cervix with 200 mg of mifepristone^a (oral) or 400 µg of misoprostol (vaginal), as it has been shown to facilitate transcervical procedures and to reduce side-effects^b.



For **very early gestations** (< 6 weeks of amenorrhea), surgical may be less effective than medical abortion (possibility of missing the gestational sac during aspiration).

^a Summary of product characteristics (<http://www.ema.europa.eu>).

^b Meirik O, et al. Complications of first-trimester abortion by vacuum aspiration after cervical preparation with and without misoprostol: a multicentre randomised trial. *Lancet* 2012;379(9828):1817-24.

WHAT INFORMATION SHOULD BE GIVEN ABOUT MEDICAL ABORTION?

Women should be advised that this method involves taking two different medications consecutively: an antiprogesterone (mifepristone) and then a prostaglandin (commonly misoprostol). Mifepristone and misoprostol induces uterine contractions leading to the expulsion of the pregnancy. For further details, please see “How does medical abortion work? How do the two medications work?”, p. 18.

The procedure includes 4 steps (counselling incl.), but depending on the country and the healthcare professional between 1 and 4 visits are necessary.

First, mifepristone is taken orally as a single dose. Then, misoprostol is taken 1 to 2 days later according to the chosen protocol via. This may be via oral route for early medical abortion ≤ 7 weeks of amenorrhea, or vaginal (commonly), sublingual or buccal route for early medical abortion ≤ 9 weeks of amenorrhea. Finally, 1 to 3 weeks after the treatment, successful expulsion should be confirmed.

For further details, please see: “How should mifepristone and misoprostol be taken?”, p. 65 and “How to exclude an ongoing pregnancy?”, p. 80.

MIFEPRISTONE INTAKE

Usually, women take **mifepristone** under clinical supervision and leave the facility without further delay, but it can be also safely taken at home if permitted by local regulations.

The woman should be informed about what to expect, including that in some cases (3%) the pregnancy can get expelled at home before she has taken the prostaglandin. She should also be informed of the possibility of bleeding (< 5% of cases).



The occurrence of bleeding after taking mifepristone does not mean that the pregnancy has been terminated. The woman still needs to take the prostaglandin.

At this step, the woman should either be given an appointment for misoprostol administration or receive the tablets to be taken at home (if permitted by local regulations). In the latter case, she will be provided with the prostaglandin and information on how to take it. She should be informed about what to expect, including side-effects. In addition, **pain treatment should be discussed, and the woman should receive sufficient pain medication.**



Expulsion usually occurs shortly (4-6 hours) after misoprostol intake; it is crucial for the woman to plan the best time for her to take the prostaglandin.

MISOPROSTOL INTAKE

There is clear evidence that it is safe for women to take **misoprostol** at home instead of coming to the healthcare facility. They should therefore be given a free choice as to where to take the misoprostol assuming that this is legally permitted in the country.

If a woman chooses to come to the healthcare facility, then she will usually remain for a few hours under observation, during which abortion occurs in around 70% of cases.

A few countries have a legal requirement for women to come to the healthcare centre to take the prostaglandin. In these countries, in case of early pregnancy (≤ 9 weeks of amenorrhea), women may choose to go home soon after administration of the prostaglandin and expel the pregnancy at home^a.

Most women will start bleeding shortly after misoprostol intake and expel the pregnancy within a few hours. However, there are huge individual variations:

- Pregnancy can be expelled before the misoprostol intake.
- A small proportion of women expel the gestational sac more than 24 hours after misoprostol intake.

During this period, most women require medication to relieve pain due to cramps. Pain medication should be made available.

^a Cameron S, et al. Women's experiences of the final stage of early medical abortion at home: results of a pilot survey. *J Fam Plann Reprod Health Care* 2010;36(4):213-6.

Women should be advised that even after expelling the pregnancy, they may expect to have bleeding which may be heavier or longer than a menstrual period. They should be given clear verbal and written information on how to reach a healthcare professional in case of abnormal bleeding or other adverse events. **A 24-hour telephone hotline should be available for all women under treatment, to answer questions or direct patients in the rare case of an emergency situation.**

For further details, please see “What are the possible complications of medical abortion? How are complications to be prevented and managed?”, p. 70.



Absence of bleeding is a sign of treatment failure.

But the occurrence of bleeding is not in itself a sign of successful abortion.

FOLLOW-UP

Successful expulsion should be diagnosed 1 to 3 weeks after the treatment, either during a follow-up visit with a skilled practitioner or with an hCG test (urinary pregnancy test at home, or serum test in a medical laboratory).



High sensitivity urinary pregnancy tests can be positive for up to 6 weeks after a successful abortion, as hCG is excreted only slowly.

The efficacy of the method is high (95%-98%). However, between 2% to 5% of women will require further medical treatment or surgery for incomplete abortion, to terminate a continuing pregnancy, or to control bleeding. For further details, please see “How to manage failure of medical abortion?”, p. 86.

The method is very safe when used as recommended. The side-effects of medical abortion are similar to those found with miscarriage: cramping and prolonged menstrual-like bleeding. Bleeding occurs for about 2 weeks on average. Side-effects may also include nausea, stomach cramps, vomiting and diarrhoea. For further details, please see “What are the main adverse events associated with medical abortion? How should they be managed?”, p. 66.

WHAT ARE THE ADVANTAGES AND DISADVANTAGES OF MEDICAL ABORTION?

The main advantages of the **medical method** are the following:

- Medical abortion can be performed at a very early stage (before 6 weeks of amenorrhea), without surgery or anaesthesia.
- Complications are very rare.
- The success of the method is not dependent on the skill of the surgeon.
- Women may feel this method is more natural and leaves them more in control than with surgery.

Its disadvantages are possible stronger pain (which can be successfully treated) and bleeding. In addition, the overall procedure takes time (for further information, please see Tab.3).

The main advantages of the **surgical method** are that the procedure is very fast, and complications are very rare when performed in a safe environment by a skilled professional in a well-equipped facility. The procedure is also highly predictable, and women can know what to expect. Some women may feel the use of anaesthesia and the loss of control as disadvantages.



Medical abortion has no effect on fertility and does not increase the risk of future miscarriage.

Tab.3 Comparison of medical and surgical abortions

Method	Medical abortion	Surgical abortion/aspiration
Performed by	<ul style="list-style-type: none"> - The patient, who takes the tablet independently. - More responsibility for the woman. 	<ul style="list-style-type: none"> - Performed by a trained professional (usually a doctor). - The professional (usually a doctor) takes the responsibility.
When	- 4 to 9 weeks of amenorrhea.	- 6 to 14 weeks of amenorrhea.
Duration	- Several days.	- 3 to 10 minutes.
Visits	<ul style="list-style-type: none"> - 1 to 4 visits (counselling incl.) depending on the country or the professional. - Possible to plan according to patient's preference. 	<ul style="list-style-type: none"> - 1 to 3 visits (counselling incl.) depending on the country or the professional. - Planned according to clinic schedule.
Additional medication	Painkillers in most cases.	Local or general anaesthesia. Painkillers.
Bleeding	More difficult to predict and control. Usually a bit stronger and longer than menstruation (i.e., 80 ml).	Same total blood loss as medical, but fewer days of bleeding after the procedure.
Complications (very rare)	Heavy bleeding, ongoing pregnancy.	Injury to the uterus, infection, problems of anaesthesia.
Side-effects	Cramp-like pain (frequent), nausea and (rarely) vomiting or diarrhoea.	Sometimes short cramp-like pain, nausea and vomiting after surgery.
Effects on fertility	None.	None if correctly performed and without complications.
Contraception	Effective method needed immediately. Hormonal contraception can be started the same day. Intrauterine device inserted at follow-up visit.	Effective method needed immediately.

^a Gynmed. Comparison of surgical and medical abortion (<http://www.gynmed.at/index.php/english/abortion/16-abortion/51-comp>).

WHAT ARE THE REASONS LEADING WOMEN TO EXPRESS A PREFERENCE BETWEEN MEDICAL AND SURGICAL ABORTION?

The most common reasons for choosing medical abortion are^{a-c}:

- Avoidance of surgery or general anaesthesia,
- Greater privacy and autonomy than surgical abortion,
- Perception that the procedure is safer and more natural than surgery.

Women tend to choose surgical abortion if they prefer to be asleep (general anaesthesia) and do not want to be aware of the procedure.



Women who choose medical abortion find it more acceptable at earlier than at later gestational ages^{d-f}.

^a Winikoff B. Acceptability of medical abortion in early pregnancy. *Family Planning Perspectives* 1995;27(4): 142-8.

^b Ho PC. Women's perceptions on medical abortion. Review article. *Contraception* 2006;74:11-5.

^c Robson SC, et al. Randomised preference trial of medical versus surgical termination of pregnancy less than 14 weeks' gestation (TOPS). *Health Technol Assess* 2009;13(53) (<http://www.hta.ac.uk/pdfexecs/summ1353.pdf>).

^d Henshaw RC, et al. Comparison of medical abortion with surgical vacuum aspiration: women's preferences and acceptability of treatment. *BMJ* 1993;307(6906):714-7.

^e Honkanen H, von Hertzen H. Users' perspectives on medical abortion in Finland. *Contraception* 2002;65(6):419-23.

^f Honkanen H, et al. WHO multinational study of three misoprostol regimens after mifepristone for early medical abortion. *BJOG* 2004;111(7):715-25.

WHAT ARE THE REASONS WHY HEALTHCARE PROFESSIONALS MIGHT PREFER TO OFFER MEDICAL OR SURGICAL ABORTION?

Medical abortion should be preferred by healthcare professionals if:

- It is the **woman's preference**.
- The **woman is severely obese** (body mass index > 30 kg/m²), as this may make surgical treatment more difficult technically.
- The woman has a **uterine anomaly** (such as bicornuate uterus), or has previously had **cervical surgery** such as conisation which may make surgical abortion technically more difficult.

Surgical abortion should be preferred if:

- It is the woman's preference.
- The woman has contraindications to medical abortion (exceptional).
- The woman has a psychological/psychiatric problem making it difficult for her to go through the process of medical abortion.



Raha SHOJAI: "Professionals should encourage shared decision making for the choice of method. Organisational barriers (e.g., waiting lists and costs) should not influence decision making."

WHY AND HOW SHOULD CONTRACEPTION METHODS BE PRESENTED DURING THE COUNSELLING VISIT?

The present unwanted pregnancy is the consequence of the absence of contraception or a failure in the contraception method. It confirms fertility in both partners.

The healthcare professional should therefore discuss with the woman (and her partner if present) what she/they had been using for contraception and how they could avoid another unwanted pregnancy in the future.

Information on contraception should be given from the first contact with the patient and an effective method can be started immediately after the abortion, because:

- Lack or failure of contraception is the main reason for an unwanted pregnancy.
- Abortion as a backup method is an integral part of comprehensive family planning. In countries where abortion is legal and widely available, abortion rates are low if effective contraception is widely used.
- Women coming for an abortion are emotionally preoccupied with the decision about the abortion and have usually spent little time thinking about contraception.
- Fertility resumes immediately, with the next ovulation taking place 10 to 14 days after abortion.
- Most women requesting abortion do not want to get pregnant again immediately.



The woman's acceptance of an effective contraceptive method must not be made a precondition for providing her with abortion services.

Post-abortion contraception is an integral part of comprehensive abortion care: abortion and contraceptive counselling and services should be provided together. For further details, please see "Which methods of contraception can a woman use after medical abortion?", p. 74.

GOOD PRACTICE POINTS

1. Legal requirements for counselling vary from country to country. **Healthcare professionals need to refer to their national law and local regulations.**
2. Women requesting an abortion should be treated with respect and understanding, ensuring confidentiality and privacy.
3. **The choice of the abortion method involves both the woman and the healthcare professional**, and will depend on several factors, including:
 - Patient preference,
 - Gestational age,
 - Patient's medical history,
 - Current national or local legislation and regulations.
4. Healthcare professionals should provide women with clear and complete information on abortion and contraception methods.
5. **A woman who chooses medical abortion needs to realise that this method involves her active participation:**
 - She needs to take the two drugs.
 - She needs to attend a check-up or perform it herself 1 to 3 weeks after taking mifepristone.
 - In some rare cases, expulsion and bleeding can occur before she takes the prostaglandin.
 - She should contact her doctor immediately in case of heavy bleeding. She should recognise signs and symptoms that may indicate a complication and for which she should seek urgent medical advice.
6. Medical abortion using combined mifepristone and prostaglandin is highly effective, but in rare cases (2% to 5%), she will require further treatment or surgery to complete the treatment.

Pre-abortion care

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The objective of this chapter is to improve:

- *Accurate estimation of gestational age*
- *Prevention of Rh-sensitisation*
- *The checklist of clinical, laboratory and ultrasound red flags for ectopic pregnancy.*

WHAT INFORMATION IS TO BE COLLECTED IN HISTORY-TAKING?

History-taking looks for any contra-indications to contraceptive and abortion methods, and screens for risk factors for complications.

Social history should include risk assessment for sexually transmissible infections, taking account of local prevalence rates.

Clinical history-taking should include:

- Personal and family history of relevant diseases, including bleeding tendencies
- Current use of medication, and known allergies
- Obstetric and gynaecological history, including ectopic pregnancies.



Teresa-Alexandra CARMO-BOMBAS: “From a clinical point of view, presence of HIV infection in a woman undergoing abortion requires the same precautions as it does in any other medical or surgical intervention.”

HOW TO CHECK GESTATIONAL AGE?

CLINICAL EXAMINATION AND PREGNANCY HISTORY TAKING

It is **difficult or sometimes impossible to diagnose early pregnancy reliably** on the basis of the woman's history and a physical examination alone.

However, history should always be taken, including:

- First day of the woman's last menstrual period,
- Whether the menses were regular,
- Any pregnancy-related symptoms: i.e., breast tenderness, nausea, vomiting, fatigue, and changes in appetite or frequency of urination. A bimanual pelvic examination can be performed to determine uterine enlargement. However, it must be kept in mind that:
- Diagnosis of gestational length by **clinical examination is not reliable in early gestation** (Tab.4).
- Bimanual pelvic examination is an invasive method.

Tab.4 Possible causes of discordant uterus size in a pregnant woman

Size of the uterus (pregnant woman)	Causes
Smaller than expected	Pregnancy less advanced than estimated Ectopic pregnancy Missed abortion
Larger than expected	Pregnancy more advanced than estimated Multiple pregnancy Presence of uterine fibroids Molar pregnancy



In case of discrepancy between uterus size on pelvic examination and gestational age, ultrasound examination should be performed.

Basic routine observations (pulse, blood pressure and temperature) are optional. They are not essential for medical abortion.

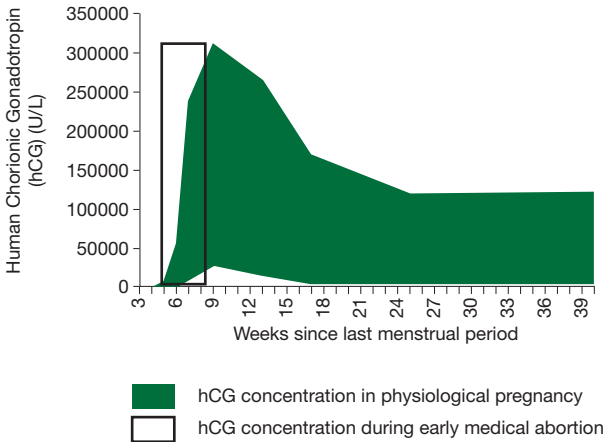
HUMAN CHORIONIC GONADOTROPIN (URINE OR SERUM)

A urinary pregnancy test that detects hCG test should be made to confirm pregnancy if ultrasound is not part of the routine examination or if the pregnancy is too early to be seen on ultrasound.

In a normal pregnancy, hCG levels double every 2-3 days between weeks 4 and 8. It is important to keep in mind the huge individual variations in hCG concentration, which prevent reliable diagnosis of gestational age based on hCG level alone. However, **hCG is positive in 98% of pregnant women at 4 weeks of amenorrhea.**

Fig.9 presents serum hCG concentration

Fig.9 Serum hCG concentration in physiological pregnancy and during early medical abortion - Adapted from Montagnana^a



The earlier the gestational age, at which medical abortion is performed, the less will be the pain and bleeding. Early diagnosis of pregnancy is therefore crucial. However, **medical abortion should not be delayed just to wait for hCG results.**

^a Montagnana M, et al. Human chorionic gonadotropin in pregnancy diagnostics. *Clin Chim Acta* 2011 17;412(17-18):1515-20.

ULTRASOUND

Ultrasound scan increases the standard of care. However, it is not always easily available, and **medical abortion can be safely performed without ultrasound.**

Where available, ultrasound can be performed to confirm viable intrauterine pregnancy and gestational age except for very early pregnancy (too small to be visualised).



Ultrasound scan **is not a prerequisite for medical abortion^a**, and lack of ultrasound should not prevent professionals from offering this method.

Where available, ultrasound scan can be performed to confirm a viable intrauterine pregnancy and date the gestational age.



Christian FIALA: “Abdominal/suprapubic ultrasound is preferred by my patients because it is less invasive. It is sufficient in the vast majority of cases to diagnose the size and viability of a pregnancy. Vaginal ultrasound should be available for specific issues.”

Ultrasound is not routinely required between mifepristone and prostaglandin administration.

Where ultrasound is used, the facility should ideally provide areas where women seeking abortion can be scanned, separate from those for women receiving antenatal care.

^a World Health Organization (WHO). *Safe abortion: technical and policy guidance for health systems*. WHO Geneva, Switzerland 2012, 124 pages.

The woman should be able to choose whether or not she wishes to look at the ultrasound screen^{a,b}.



Kristina GEMZELL-DANIELSSON: “We always allow women to choose whether they want to look at the ultrasound screen or not.”

Definitive diagnosis of intrauterine pregnancy by ultrasound scan requires detection of:

- **Gestational sac**

It is visible (6 to 10 mm diameter) from around 35 days of amenorrhea (5 weeks). An excentric location and decidual reaction may differentiate a true gestational sac from a pseudo-sac (often central, with no decidual reaction), although this sign alone is not always sufficient.

- **Yolk sac**

It is visible (diameter 3 to 8 mm) from around 38 days of amenorrhea and should be visible. Its presence is proof of intrauterine pregnancy.

- **Embryo**

It appears at 42 days of amenorrhea (6 weeks). Cardiac activity can be detected in a 2-3 mm embryo and is systematically detected in a 5 mm embryo.

^a Wiebe ER, Adams L. Women's perceptions about seeing the ultrasound picture before an abortion. *Eur J Contracept Reprod Health Care* 2009;14(2):97-102.

^b Bamigboye AA, et al. Should women view the ultrasound image before first trimester termination of pregnancy? *S Af Med J* 2002;92(6):430-2.

Diagnosis of intrauterine pregnancy does not necessarily exclude presence of ectopic pregnancy. Heterotopic pregnancy (with one intrauterine and one ectopic gestation) can occur, but is extremely rare in women not using assisted reproduction technologies.



A gestational sac with a yolk sac is proof of intrauterine pregnancy.

A gestational sac of 16 mm diameter or more normally contains a viable embryo.

An embryo of 5 mm diameter or more normally has cardiac activity.

Gestational age can be determined by measuring the gestational sac or the longest axis (crown-rump length, CRL) of the embryo, when visible:

Gestational age (days) = diameter of the gestational sac (in mm) + 30

Gestational age (days) = CRL (in mm) + 42.

Training in ultrasound in abortion care can be helpful. An interactive training CD and workbook (Ultrasound in Abortion Care, by Deutchman M et al.^a) can be recommended.

^a Affiliates Risk Management Services, New York, USA. Available at: arms@armsinc.org

SHOULD ANTI-D PROPHYLAXIS BE ADMINISTERED TO RH-NEGATIVE WOMEN?

Most clinical guidelines recommend Rh-immunisation in Rh-negative women, without specifying a lowest gestational age.

For pregnancies ≤ 9 weeks of amenorrhea, there is no evidence that maternal Rh-sensitisation occurs during spontaneous or induced abortion. However to prove Rh-immunisation is not necessary is difficult, even when the theoretical risk is very low.

In countries where the prevalence of Rh-negative status is high (e.g., in Caucasian women), and if resources permit, maternal Rh-typing and anti-D prophylaxis might be offered as precautionary components of complete medical abortion care. In that case, it is recommended to administer a dose of 50 μg (250 IU) anti-D immunoglobulin G (IgG)^a. This dose can neutralise more than 2 ml of foetal blood in the maternal circulation. The Rh-immunoglobulin can be given on the same day that mifepristone or misoprostol is administered^b.

^a World Health Organization (WHO). *Safe abortion: technical and policy guidance for health systems*. WHO Geneva, Switzerland 2012, 124 pages.

^b Fiala C, et al. *Rh-prophylaxis in early abortion*. *Acta Obstet Gynecol Scand* 2003;82(10):892-903.

WHAT OTHER TESTS OR EXAMINATIONS SHOULD BE PERFORMED?

The following tests or examinations should be performed only if there are clear clinical indications.

- **Cervical cytology**

Unscheduled cervical screening is not justified if the woman is less than 21 years of age or has undergone screening within the previous 3 to 5 years, unless the previous screening test was abnormal.

Cervical cytology is not necessary before medical abortion. If a woman has been called for routine screening and she is pregnant and coming for an abortion, the test will be deferred until after the medical abortion unless there is a specific indication^a.



Teresa-Alexandra CARMO-BOMBAS: “In women that were not regular attendees of Family Planning Services, the appointment for medical abortion can be an opportunity for cervical screening.”

- **Laboratory testing for reproductive tract infection**

If clinical signs indicate infection, the woman must be treated with antibiotics immediately. However, this should not delay the beginning of medical abortion treatment.

- **Other laboratory tests**

There is no indication for:

- Routine coagulation tests in low-risk asymptomatic women with no personal or family history of excessive bleeding,
- Haemoglobin and haematocrit assays in the absence of clinical signs of anaemia.

a Luesley D, Leeson S, editors. Colposcopy and programme management. Guidelines for the NHS Cervical Screening Programme. 2nd edition. Sheffield: NHS Cancer Screening Programmes, 2010
(<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp20.html>).

WHAT ARE THE CONTRAINDICATIONS AND PRECAUTIONS FOR USE FOR MEDICAL ABORTION?

Medical abortion is a very safe treatment with extremely few contraindications. However, **pregnancy has to be confirmed by ultrasound scan or biological tests prior to the treatment.**

Medical abortion **is not to be given** in women with^a:

- Adrenal failure,
- Allergy (hypersensitivity) to the active substance (mifepristone) or any of the excipients of Mifegyne[®],
- Allergy (hypersensitivity) to the chosen prostaglandin,
- Severe asthma uncontrolled by therapy,
- Inherited porphyria,
- Known ectopic pregnancy or specific signs or symptoms suggesting ectopic pregnancy.



Medical abortion is not effective in ectopic pregnancies.

Medical abortion **is not recommended** in women suffering from:

- Renal failure,
- Hepatic failure,
- Malnutrition,
- Any illness or treatment that negatively affects blood clotting,
- Severe anaemia,
- Uncontrolled epilepsy.

Medical abortion with E1-prostaglandins (such as misoprostol) is not contraindicated in women with controlled asthma, cardiovascular history or a risk factor for heart disease, such as high blood pressure or high blood cholesterol level. This is in contrast to E2-prostaglandins (dinoprostone, marketed as Cervidil[®], Prostin E2[®], Propess[®], Glandin[®]), which are contraindicated in these situations.

^a Summary of product characteristics (<http://www.ema.europa.eu>).

The following medications may decrease the efficacy of medical abortion, as they decrease the serum level of mifepristone: phenytoin, phenobarbital or carbamazepine. Conversely, mifepristone reduces the activity of rifampicin, dexamethasone and St John's wort (*Hypericum perforatum*).

The following situations are not contraindications for medical abortion: age, type-2 diabetes, thyroid disorder, multiple pregnancy, obesity, previous caesarean section, smoking, uterine malformation and previous cervical surgery. For further details, please see, "Are there specific measures to apply in case of ...?", p. 92.

The levels of **mifepristone** found in mother's breast milk are low and not expected to be of clinical relevance^a. **Misoprostol** is rapidly metabolised to misoprostol acid, which is biologically active and excreted in breast milk. The level of misoprostol acid is low in breast milk and rapidly declines after a single dose of 200 µg or 600 µg. No clinical effects are expected at such low doses. **Based on available evidence, the doses of mifepristone and misoprostol used in medical abortion allow nursing to be safely continued without interruption.**

^a Sääv I, et al. Medical abortion in lactating women--low levels of mifepristone in breast milk. *Acta Obstet Gynecol Scand* 2010;89(5):618-22

IS PREGNANCY LOCATION REQUIRED IN VERY EARLY PREGNANCY? HOW CAN ECTOPIC PREGNANCY BE DIAGNOSED?

More and more women are self-diagnosing their pregnancy very early and presenting for abortion as soon as they miss a period or shortly thereafter. In these cases, the location of the pregnancy cannot be diagnosed, due to its small size.

Although ectopic pregnancy cannot be ruled out (these women do not necessarily present with signs allowing positive diagnosis), **medical abortion can be started without delay if close follow-up** (i.e., pre- and post-hCG assay) **after 1 week can be scheduled.** Indeed, side-effects such as pain and bleeding are at their lowest when abortion is performed in very early pregnancy, and increase with gestational age.



There is no need to delay the treatment until a yolk sac or foetal cardiac activity can be seen on ultrasound

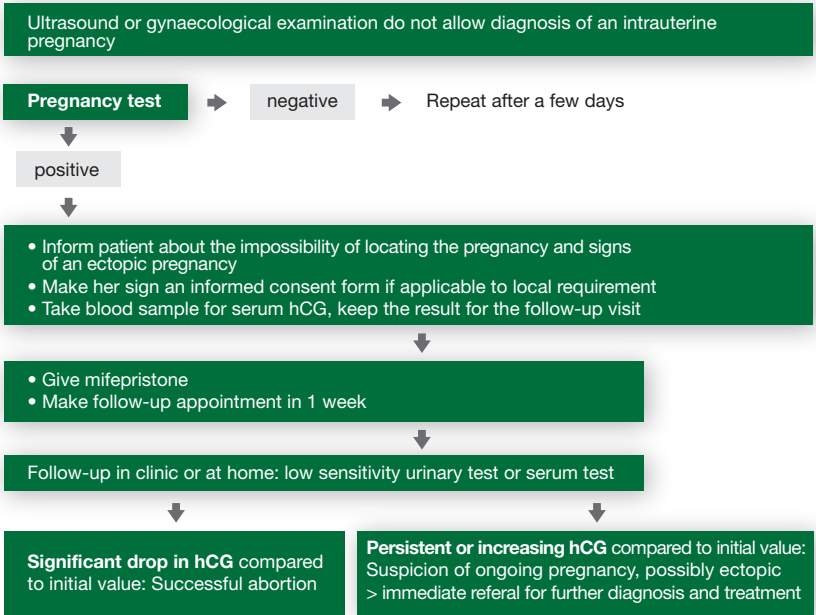
ECTOPIC PREGNANCY

Ectopic/extrauterine pregnancy is a rare but potentially life-threatening event. Failing to detect it in patients coming for abortion in very early pregnancy is therefore one of the main worries of healthcare professionals. **Women with specific signs and symptoms of ectopic pregnancy should be referred to an appropriate gynaecological facility without delay.**

Diagnosis can be difficult, and is actually impossible in very early gestation. Therefore a specific procedure should be used in all facilities, so as to ensure against overlooking any ectopic pregnancy. If this can be implemented, then women in very early pregnancy should be given the option of starting treatment without delay.

Fig.10 shows a model flow-chart for patients presenting very early for abortion.

Fig.10 Procedure for patients presenting very early for an abortion



Risks factors for ectopic pregnancy are the following:

- Previous ectopic pregnancy,
- Previous fallopian tube surgery including sterilisation,
- Documented fallopian tube pathology,
- In utero diethylstilboestrol (DES) exposure,
- Previous genital infection (chlamydia, gonorrhoea, pelvic inflammatory disease),
- Infertility.



If ectopic pregnancy is suspected based on specific symptoms, diagnosis must be confirmed and treatment initiated immediately.

Clinical diagnosis of ectopic pregnancy by clinical examination alone is difficult or impossible.

The following signs are possible red flags:

- Constant lower abdominal pain on one side, especially if accompanied by vaginal bleeding and spotting, dizziness or fainting, pallor and, in some women, an adnexal mass touching the uterus
- Uterine size smaller than expected for the estimated duration of pregnancy
- Peritoneal irritation signs and pain on moving the uterus.



If medical abortion has been started without prior confirmation that the pregnancy is intrauterine, and the woman has constant severe and increasing pain on one side of the lower abdomen during or after the procedure (with increase in hCG level), ectopic pregnancy must be suspected and appropriate tests performed without delay.

The most reliable way to diagnose ectopic pregnancy is by serum hCG and ultrasound imaging.

A discrepancy between serum hCG levels and ultrasound findings can be suggestive of ectopic pregnancy, even in the absence of clinical symptoms.

However, serum hCG levels are subject to huge individual variations. Published correlations between hCG and ultrasound are therefore only indicative and can diverge significantly between individual patients.

An hCG level above 1,500 mIU/ml (Fig.9, p. 49) with absence of intrauterine gestational sac on vaginal probe can be suggestive of ectopic pregnancy.

GOOD PRACTICE POINTS

1. Pregnancy must be diagnosed with reliable methods such as ultrasound and/or hCG.
 - **Ultrasound** has the advantage allowing reliable dating and diagnosis of associated conditions.
 - **hCG** has the advantage of also being reliable in very early pregnancy.
 - **Gynaecological examination** can be useful in settings where other forms of diagnosis are not readily available.
2. Where ultrasound scan is used, the facility should, if possible, provide areas where women seeking abortion can be scanned, separate from those for women coming for antenatal care.
3. **Medical abortion should be performed as soon as the patient has made up her mind and ongoing pregnancy has been diagnosed.**
5. In countries where the prevalence of Rh-negative status is high, and in settings with resources, **Rh-typing and anti-D prophylaxis may be offered** as precautionary measures, even though there is no evidence of maternal Rh sensitisation in abortion during the first 9 weeks of amenorrhea.
6. Unless there are specific indications, **cervical cytology and other laboratory tests are not necessary before medical abortion** and the procedure should not be delayed awaiting laboratory or other results unless they are important for the safety of the procedure.

Medical abortion treatment

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The objective of this chapter is to improve:

- *Knowledge of medical abortion treatment*
- *Management of adverse events*
- *Prevention and management of complications.*

WHAT ARE THE RECOMMENDED PROTOCOLS IN EARLY PREGNANCY?

Medical termination of pregnancy using mifepristone followed by misoprostol is a highly effective method (for further information, please see “How does medical abortion work? How do the two medications work?”, p. 18).

The two drugs are to be taken in sequence to be more effective in expelling the pregnancy. Simultaneous intake of the two medications is considerably less effective than sequential.



Respect of a time-interval between mifepristone and the prostaglandin is important. Myometrium sensitisation to prostaglandin is maximal with a 36-48 hour interval. In practice, time-interval can be shortened to 24 hours, provided sufficient prostaglandin is administered.

For the first trimester of pregnancy, there are numerous protocols according to gestational age and setting. The most recent is an updated evidence-based cost-effective protocol published by the WHO^a.

Recommendations usually distinguish very early pregnancy (before 7 weeks of amenorrhea) from later gestational bands (7 to 9 weeks of amenorrhea).

Although dose and administration route differ between guidelines, the efficacy, safety and acceptability of medical abortion are extremely high in all cases.



Implementation of the medical abortion method must be in accordance with national legislation.

Tab.5 and Tab.6 show the different recommended regimens for early medical abortion, before 7 weeks and between 7 and 9 weeks of amenorrhea, respectively^b.

^a World Health Organization (WHO). *Safe abortion: technical and policy guidance for health systems*. WHO Geneva, Switzerland 2012, 124 pages.

^b FIAPAC (<http://www.fiapac.org/pages/en/links/links-5.php>).

Tab.5 Various recommendations for early medical abortion before 7 weeks of amenorrhoea

Recommendations (Year)		Mifepristone* Dose	Prostaglandin Product, Route (Dose)		Time interval (Hours)
EMA HAS	2007 2010	600 mg	Misoprostol	Oral (400 µg)	36-48
EMA	2007	600 mg	Gemeprost	Vaginal (1 mg)	36-48
		200 mg	Gemeprost	Vaginal (1 mg)	36-48
RCOG WHO	2011 2012	200 mg	Misoprostol	Vaginal/ Sublingual/ Buccal (800 µg)	24-48
				Oral (400 µg)	24-48

Tab.6 Various recommendations for early medical abortion between 7 and 9 weeks of amenorrhoea

Recommendations (Year)		Mifepristone* Dose	Prostaglandin Product, Route (Dose)		Time interval (Hours)
EMA HAS	2007 2010	600 mg	Gemeprost	Vaginal (1 mg)	36-48
		200 mg	Gemeprost	Vaginal (1 mg)	36-48
HAS RCOG WHO	2010 2011 2012	200 mg	Misoprostol	Vaginal/Buccal/ Sublingual (800 µg)	24-48

* Oral route. G

EMA: European Medicine Agency; HAS: Haute Autorité de Santé (France); RCOG: Royal College of Obstetricians and Gynaecologists (UK); WHO: World Health Organisation.

The following protocol is widely used for pregnancies before 7 weeks of amenorrhoea: 3 tablets of mifepristone taken orally (200 mg/tablet, total dose: 600 mg), followed 36 to 48 hours later by 2 tablets of misoprostol taken orally (200 µg/tablet, total dose: 400 µg).

The following protocol is widely used for pregnancies between 7 and 9 weeks of amenorrhoea: 1 tablet of mifepristone taken orally (200 mg/tablet, total dose: 200 mg) followed 36 to 48 hours later by 4 tablets of misoprostol inserted vaginally (200 µg/tablet, total dose: 800 µg).

HOW SHOULD MIFEPRISTONE AND MISOPROSTOL BE TAKEN?

The following protocol concerns early medical abortion with mifepristone and misoprostol. The different protocols are shown in Tab.5 and Tab.6. For further details on each step of the medical abortion procedure, please see “What information should be given about medical abortion?”, p. 33.

MIFEPRISTONE INTAKE

Mifepristone is taken orally in a single dose. Usually, it is taken in the presence of a healthcare professional, but could be taken safely at home if permitted by local legislation. When mifepristone is taken in the healthcare setting, the woman may leave the facility without further delay.



For pregnancies that have occurred despite an intrauterine device, the device should be removed prior to administering mifepristone.

MISOPROSTOL INTAKE

Misoprostol can be taken at home or in the healthcare facility. In women with severe vomiting in early pregnancy, it is preferable to administer the prostaglandin vaginally rather than orally. Another dose of misoprostol can be taken again if bleeding does not start in a menstrual-like way 3 hours after the first dose.



When they can choose, women usually prefer the oral route.^a

^a Aubeny E, Chatellier G. A randomized comparison of mifepristone and self-administered oral or vaginal misoprostol for early abortion. *Eur J Contracept Reprod Health Care* 2000;5(3):171-6.

WHAT ARE THE MAIN ADVERSE EVENTS ASSOCIATED WITH MEDICAL ABORTION? HOW SHOULD THEY BE MANAGED?

When performed by skilled healthcare professionals with proper equipment, correct technique and standards, abortion is one of the safest medical procedures.



The most frequently reported adverse events in medical abortion are **pain** (caused by uterine contractions) and **vaginal bleeding**.

Diarrhoea, headache, malaise and a rise in body-temperature, which may occur, usually with prostaglandin, are dose-dependent and less frequently reported.

PAIN

Pain is caused both by uterus contractions due to the prostaglandin and by the expulsion of the gestational sac. It is usually greatest in the first few hours after administration of the prostaglandin, and decreases after the pregnancy has been expelled from the uterus.

Pain increases with pregnancy size. It may be milder in older women and women who have been pregnant before.



Severe constant pain still felt several days after administration of the prostaglandin requires careful attention, as it may be related to infection.

Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen 200 mg, can be taken systematically following misoprostol^a. Acetaminophen (paracetamol) can also be used but it is less effective than ibuprofen. In rare cases of severe pain, codeine (50-60 mg) may be added.

^a World Health Organization (WHO). *Safe abortion: technical and policy guidance for health systems*. WHO Geneva, Switzerland 2012 pp124.



Kristina GEMZELL-DANIELSSON: “We always offer ‘prophylactic pain medication’ -that is, NSAIDs- before administration of misoprostol. Reducing pain helps women to relax and thus leads to a shorter induction-to-expulsion interval.”

Abdominal massage, a hot-water bottle or heating pad, sitting or lying comfortably and support from friends and family can all help to relieve pain.



Women should be instructed to take painkillers at the same time as the prostaglandin analogue.

BLEEDING

Bleeding usually occurs a few hours after prostaglandin administration. It is usually heavy, with clots, and lasts for 2 to 4 hours. It then decreases, and slight bleeding continues for an average of about 2 weeks. In some cases, bleeding can continue up to the next menstrual bleeding. Bleeding duration and volume increase with pregnancy duration and are greater after 7 weeks of amenorrhea than in very early pregnancy.

Bleeding can best be managed if women are counselled on what to expect and when to seek treatment if bleeding becomes very heavy or persists for a long time. In addition, women should have adequate access to emergency back-up facilities and healthcare professionals on a

24 hour-basis in case of excessive bleeding (for further details, please see “Haemorrhage”, p. 70).



Christian FIALA: “Prolonged slight bleeding does not increase the risk of infection and is not a medical indication to abstain from sexual intercourse.”

The following questions can help the healthcare professional to determine bleeding severity:

- “Did you take mifepristone?”; “Did you take misoprostol?”
- “Did you take other medicines?”
- “How many sanitary towels did you use during the last 2 or 3 hours?”
- “Did you see clots?”; “Did you see the pregnancy?”
- “Is the bleeding continuous or episodic?”
- “Do you have other clinical signs (malaise, faintness or weakness)?”

Excessive bleeding is considered as soaking more than 2 or 3 sanitary pads per hour for more than 2 or 3 hours.

In the vast majority of cases, no treatment is needed. However, in case of signs of severe bleeding the woman should be transferred to a hospital.

GASTROINTESTINAL SIDE-EFFECTS

Nausea and vomiting are frequent pregnancy-related symptoms. In some cases they may become worse with treatment. Diarrhoea can be caused by the action of prostaglandin on the intestinal muscle fibres. **Gastrointestinal side-effects are transient and dose-related.** They usually occur within the hour following administration and last for 1 to 2 hours.

In case of severe symptoms, anti-emetic and anti-diarrhoeic drug treatments should be provided.

OTHER CLINICAL SIGNS

Transient (1 to 3 hours) rise in **body temperature** may occur after prostaglandin administration. Symptomatic treatment and reassurance can be provided.



Any body temperature of 38°C or higher lasting for more than 3 hours or occurring more than 12 hours after prostaglandin administration must be explored (possible infection).

Shivering, hypothermia, malaise and abnormal vaginal discharge may be associated with infection, and are indications that the woman requires medical attention.

Transient headache occurs in approximately a quarter of women undergoing medical abortion. Reassurance, and analgesia if needed, may be provided.

WHAT ARE THE POSSIBLE COMPLICATIONS OF MEDICAL ABORTION? HOW ARE COMPLICATIONS TO BE PREVENTED AND MANAGED?

Complications after medical abortion are rare, and include severe haemorrhage and infection (continuing pregnancy being counted rather as treatment failure).

Before prescribing mifepristone, women must therefore be informed about the low risk of these events. **Women have to know whom to call and what to do** (including going to an Emergency Department if none of the provided contact-persons are reachable) **if they experience sustained fever, shivering, severe abdominal pain, prolonged heavy bleeding, or fainting.**

HAEMORRHAGE

Prolonged or heavier than menstrual bleeding is an expected effect of medical abortion. **Bleeding excessive enough to warrant either blood transfusion or back-up curettage (aspiration) is extremely rare** (0%-0.2% and 0.3%-2.6% of cases, respectively).

Every facility must be able to stabilise and treat women with haemorrhage, or refer them elsewhere, as quickly as possible.

- If there is evidence of haemodynamic shock, intravenous fluids should be administered
- If bleeding is particularly profuse or prolonged, surgical intervention may be required
- Transfusion should be performed only if clearly medically required.

Women should be advised to seek immediate medical attention if they experience prolonged heavy vaginal bleeding, as it may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed.

INFECTION

The genital tract is more susceptible to ascending infection when the cervix is dilated after abortion or childbirth. Infection (endometritis, pelvic inflammatory disease, PID) is a rare complication but depends on individual risk factors. While the risk in medical abortion is lower than in the surgical method, it still exists and is similar to that found in spontaneous abortion. Infection has been reported in less than 5% of women after medical abortion.

Common symptoms of infection include fever or chills, foul-smelling vaginal or cervical discharge, persistent abdominal or pelvic pain, prolonged vaginal bleeding or spotting, and uterine tenderness.



Severe pain after completed expulsion can be related to infection and requires careful attention, even in the absence of fever.

When infection is suspected and/or diagnosed, antibiotics should be administered and, if retained products of conception are a likely cause of the infection, the uterus should be evacuated and antibiotics administered. Hospital admission may be necessary in case of severe infection.

Antibiotic prophylaxis is prescribed in some countries (e.g., the UK), for reasons based on cost-effectiveness and local frequency of infection.

Routine use of prophylactic antibiotics is not recommended^a.

^a World Health Organization (WHO). *Safe abortion: technical and policy guidance for health systems*. WHO Geneva, Switzerland 2012, 124 pages.



Régine SITRUK-WARE: “Fifteen cases of toxic shock caused by *Clostridium sordellii* endometritis have been reported after medical abortion. Out of the 11 cases that were fatal, 10 were reported after medical abortion with 200 mg mifepristone followed by vaginal administration of misoprostol tablets and 1 after medical abortion with 200 mg mifepristone followed by buccal administration of misoprostol tablets. These cases of fatal sepsis had atypical presentations: leucocytosis, tachycardia, haemoconcentration, and general malaise **without fever**, bacteraemia or significant findings on pelvic examination. Although similar events can occur after delivery, caesarean section, or miscarriage, **health care professionals should be aware of the possible occurrence of this very rare but potentially life-threatening event.**”

OTHER COMPLICATIONS

The vast majority of women who have a medical abortion will not suffer any long-term effects on their general or reproductive health. On the contrary, the present pregnancy confirms fertility and the next ovulation usually occurs 10-14 days after medical abortion.

WHAT MUST THE WOMEN KNOW BEFORE TAKING THE FIRST DRUG?

Women should be aware of:

- The dates of the forthcoming visits.
- The possibility (< 5% of cases) of bleeding after taking mifepristone.
- The possibility of expulsion (3%) after taking mifepristone.
- How to take the prostaglandin (if to be taken at home) and repeated doses.
- The amount of bleeding and pain they can expect (which may be significantly stronger than normal menstrual cramps).
- The usefulness of ibuprofen or paracetamol to relieve pain.
- How and when to seek urgent medical attention.
- The use of sanitary pads to assess bleeding.
- When to start contraception, and with which method.
- How the success of abortion will be checked.

In very rare cases medical abortion is not effective and the pregnancy continues. The teratogenic risk to the foetus in these situations is at present unknown; the woman should therefore be aware that if medical abortion fails and she has an ongoing pregnancy:

- Then termination should be completed by either medical or surgical abortion.
- If she wishes to continue with the pregnancy, careful ultrasound monitoring is advised, as malformation risk cannot be ruled out (For further details, please see “Is there a risk of foetal abnormality after unsuccessful medical abortion?”, p. 87).

Women should be aware that mifepristone and misoprostol are absorbed rapidly when taken orally. Consequently, if vomiting occurs 1.5 hours or more after taking either drug, there is no need to take the drug again.

Finally women must be aware that **fertility resumes immediately after medical abortion**. It has been shown that ovulation may occur as early as 10 days after a first-trimester abortion and, in one study, up to 78% of women had ovulated by 6 weeks. Consequently, they are able to become pregnant again almost immediately.

WHICH METHODS OF CONTRACEPTION CAN A WOMAN USE AFTER MEDICAL ABORTION?

The woman should be provided with accurate information to assist her in choosing the most appropriate contraceptive method to meet her needs. However, the final choice must be her own.



Women who choose a contraceptive method that cannot be started immediately should be encouraged to use condoms and receive a prescription for emergency contraception.

Women may start:

- Hormonal contraception on the day of prostaglandin intake or the day after.
- Intrauterine device use as soon as complete abortion has been diagnosed.
- Caps, sponges, diaphragms, spermicidal foams, jellies or vaginal tablets as soon as sexual intercourse is resumed.
- Methods based on fertility awareness once regular menstrual cycles have resumed.

For further details, please see “When should contraception be started after abortion?”, p. 83.

GOOD PRACTICE POINTS

1. **Medical abortion using mifepristone followed by misoprostol is a highly effective medical procedure.** Oral misoprostol is effective before 7 weeks of amenorrhea but not after 7 weeks. After 7 weeks, misoprostol should be taken via another route (vaginal, sublingual, or buccal).
2. **Medical abortion is a very safe medical procedure:** serious adverse events (haemorrhage or infection) are rare and the most common adverse events (pain, bleeding and gastrointestinal disorders) directly related to abortion and/or prostaglandin effects are the same as those found in case of miscarriage.
3. **Women must be informed of the risk of severe adverse events, be able to identify clinical signs that help to diagnose these complications, and know what to do in these cases.**
4. Very rare cases of fatal toxic shock caused by *Clostridium sordellii* endometritis presenting without fever or other obvious symptoms of infection have been reported in different situations such as delivery and spontaneous abortions as well as with medical abortion.
5. **Analgesic drugs** (ibuprofen or paracetamol) as well as such simple techniques as a hot water bottle, abdominal massage, etc. **can be used to relieve pain.** Prophylactic antibiotics are not routinely required for medical abortion.
6. Medical abortion drugs (mifepristone or misoprostol) should be taken again in case of vomiting within 1.5 hours of intake.

Post-abortion care

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This chapter covers:

- *Methods of follow-up after medical abortion*
- *Excluding ongoing pregnancy in medical abortion*
- *Contraception after medical abortion*

WHAT IS THE PURPOSE OF FOLLOW-UP AFTER MEDICAL ABORTION?

The purpose of follow-up after medical abortion is basically to confirm that the pregnancy has been successfully terminated.

Further goals are:

- To ensure that effective contraception has been commenced,
- To detect complications,
- To provide psychological support.

However, rather than waiting for a follow-up visit before starting contraception, women should be advised to begin immediately after the medical abortion.

Furthermore, complications such as haemorrhage or infection may occur before a scheduled follow-up visit. Women should therefore be given clear advice about signs and symptoms that may indicate a complication, and be advised to seek prompt medical advice.

Only a minority of women experience ongoing psychological difficulties after an abortion. Rather than a routine follow-up visit, women should be provided with information about where they can seek advice and support after the abortion if they do experience ongoing grief or sadness.



If the woman has expelled the pregnancy on hospital/clinic premises and passage of products of conception has been confirmed by an experienced clinician, then no routine follow-up is necessary unless bleeding (heavier than regular menses) persists for more than 9 days.

HOW TO EXCLUDE AN ONGOING PREGNANCY?

ULTRASOUND

An ultrasound scan will reliably exclude ongoing pregnancy if an intrauterine pregnancy was visible on ultrasound before treatment. Blood clots or thick endometrium are common ultrasound findings in the uterine cavity, and are not usually clinically relevant.

Ultrasound can increase the standard of care and facilitate medical abortion, but can be expensive and is therefore not always available. Ultrasound can lead inexperienced clinicians to carry out unnecessary interventions (evacuation of the uterus) due to the presence of ultrasonically visible but clinically unimportant blood clots^{a-f}.



Christian FIALA: “A frequent mistake is to misdiagnose the intrauterine blood clots as residual products of conception. Indications for back-up curettage should therefore be based on clinical signs instead of ultrasound findings, except in the case of ongoing pregnancy”.



In the case of a very early pregnancy, ultrasound is not useful to confirm expulsion. Follow-up should be based on hCG measurement.

^a Acharya G, et al. Role of routine ultrasonography in monitoring the outcome of medical abortion in a clinical setting. *Acta Obstet Gynecol Scand* 2004;83(4):390–4.

^b Cowett AA, et al. Ultrasound evaluation of the endometrium after medical termination of pregnancy. *Obstet Gynecol* 2004;103(5pt1):871–5.

^c Mc Ewing RL, et al. Sonographic appearances of the endometrium after termination of pregnancy in asymptomatic versus symptomatic women. *J Ultrasound Med* 2009;28(5):579–86.

^d Rufener SL, et al. Sonography of uterine abnormalities in postpartum and postabortion patients: A potential pitfall of interpretation. *J Ultrasound Med* 2008;27(3):343–8.

^e Reeves MF, et al. Endometrial thickness following medical abortion is not predictive of subsequent surgical intervention. *Ultrasound Obstet Gynecol* 2009;34(1):104–9.

^f Fiala C, et al. Verifying the effectiveness of medical abortion; ultrasound versus hCG testing. *Eur J Obstet Gynecol Reprod Biol* 2003;109:190–5.

HCG TESTING COMBINED WITH INTERVIEW ABOUT BLEEDING AND PREGNANCY SYMPTOMS

Within 24 hours of misoprostol intake, there is a marked decrease (70%) in serum hCG level, followed by a more gradual decline. By 2 weeks after medical abortion, hCG levels are reduced by 99%^a. It takes about 7 to 8 weeks for hCG to become undetectable^b.

Serum measurements of hCG before and after medical abortion have been used to exclude ongoing pregnancy^b. In a study of women at less than 7 weeks' gestation, a fall in hCG of less than 20% of the initial value had a positive predictive value of 95%. However, serum hCG testing is time-consuming and serum hCG level correlates very well with urine concentrations^c.

Although the usual urine pregnancy tests on their own are not a sufficiently reliable method for detecting ongoing pregnancy, even low-sensitivity urine pregnancy tests (LSUP) can, in combination with a series of questions about bleeding and presence of pregnancy symptoms, be used to screen for ongoing pregnancy^{d-f}.

^a Honkanen H, et al. *The kinetics of serum hCG and progesterone in response to oral and vaginal administration of misoprostol during medical termination of early pregnancy.* Hum Reprod 2002;17:2315-9.

^b Fiala C, et al. *Verifying the effectiveness of medical abortion; ultrasound versus hCG testing.* Eur J Obstet Gynecol Reprod Biol 2003;109:190-5.

^c Grossman D, et al. *Accuracy of a semi-quantitative urine pregnancy test compared to serum beta-hCG measurement: a possible screening tool for ongoing pregnancy after medication abortion.* Contraception 2007;76:101-4.

^d Clark W, et al. *Alternatives to a routine follow-up visit for early medical abortion.* Obstet Gynecol 2010;115(2Pt1):264-7.

^e Perriera LK, et al. *Feasibility of telephone follow-up after medical abortion.* Contraception 2010;81(2):143-9.

^f Cameron ST, et al. *Telephone follow-up and self-performed urine pregnancy testing after early medical abortion: a service evaluation.* Contraception 2012 [Epub ahead of print].

Women who screen positive on the basis either of a positive LSUP or of minimal bleeding during the treatment or ongoing pregnancy symptoms at follow-up require a confirmatory ultrasound or serum hCG testing.



The urine pregnancy test can be performed by the woman herself at home or, if preferred, in the facility.

An LSUP that detects urine hCG levels of 1,000 IU has been used at 2 weeks after medical abortion, in combination with questions about bleeding and symptoms, to screen for ongoing pregnancy.

The high-sensitivity urine pregnancy test (HSUP), which detects lower levels of urine hCG (in the region of 25 IU), usually found in pharmacies cannot be used until 4 weeks after medical abortion.

This method of follow-up can be conducted via a telephone call to the woman (if she is at home), together with a self-performed LSUP at 2 weeks (or HSUP at 4 weeks).



Sharon CAMERON: “Ongoing symptoms of pregnancy, tender breasts, feeling sick, tummy growing, no bleeding within 24 hours of treatment, bleeding lasting less than 4 days, or no period by 1 month after treatment should, even with a negative pregnancy test, be taken as an indication for clinical examination to exclude ongoing pregnancy”

WHEN SHOULD CONTRACEPTION BE STARTED AFTER ABORTION?

Medical abortion has no adverse effects on fertility or the outcome of a subsequent pregnancy. Ovulation may return as early as 8 to 10 days after an induced abortion with no difference between medical and surgical abortion, and 83% of women have ovulation during the first cycle after abortion^{a,b}. In addition, more than 50% of women have been found to reinstate sexual activity within two weeks after the induced abortion^c.



Contraception should be started immediately after medical abortion.

A small proportion of abortions are repeat abortions. Postponing contraception is associated with the highest rate of repeat abortion^d. Women who start using an intrauterine method immediately after their abortion have a significantly lower rate of repeat abortions.

The WHO's Medical Eligibility Criteria and Selected Practice Recommendations for Contraceptive Use (WHOMEC and WHOSPR, respectively) provide evidence-based recommendations on eligibility for methods and on maximising effective contraceptive use. The WHOSPR advises that all hormonal methods (pills, injectables, implants, patches, rings) can be started on the same day as misoprostol administration.

Commencing a combined hormonal pill does not affect the number of days of bleeding or measured blood loss after early medical abortion^e. While there is no direct evidence, it seems likely that this is also the case for combined hormonal contraceptives by other routes (transdermal, vaginal).

^a Lähteenmäki P, Luukkainen T. Return of ovarian function after abortion. *Clin Endocrinol* 1978;8:123-32.

^b Schreiber CA, et al. Ovulation resumption after medical abortion with mifepristone and misoprostol. *Contraception* 2011;84:230-3.

^c Boesen HC, et al. Sexual behavior during the first eight weeks after legal termination of pregnancy. *Acta Obstet Gynecol Scand* 2004;83:1189-92.

^d Heikenheimo O, et al. Age, parity, history of abortion and contraceptive choices affect the risk of repeat abortion. *Contraception* 2008;78(2): 149-54.

^e Tang OS, et al. The Effect of Contraceptive Pills on the Measured Blood Loss in Medical Termination of Pregnancy by Mifepristone and Misoprostol: a Randomized Placebo Controlled Trial. *Human Reproduction* 2002;17:99-102.

WHEN TO INSERT AN INTRAUTERINE DEVICE?

Early insertion of the copper intrauterine device (IUD) or levonorgestrel intrauterine system (IUS) is safe, well-tolerated, and is not associated with an increased risk of expulsion or complication.

Women are more likely to return for IUD/IUS fitting and less likely to have had prior unprotected intercourse if fitting is scheduled soon after the abortion.

Early fitting should be routinely suggested for women undergoing first-trimester medical abortion^{a,b}.

Intrauterine contraceptives (IUD/IUS) can be inserted when complete abortion has been diagnosed (e.g., at follow-up visit or after the next menstruation).

Women who choose to have an IUS after abortion have significantly fewer days of heavy bleeding after the procedure^c.

If insertion of an IUD/IUS has to be delayed, then the woman should be provided with an interim method of contraception to use after the abortion, until the IUD/IUS can be inserted.

^a Shimoni N, et al. *Timing of Copper Intrauterine Device Insertion After Medical Abortion. Obstet Gynecol* 2011;118:623-8.

^b Betstadt SJ, et al. *Intrauterine device insertion after medical abortion. Contraception* 2010;83:517-21.

^c Bednarek PH, et al. *Immediate versus delayed IUD insertion after uterine aspiration. N Engl J Med* 2011;364:2208-17.

WHAT PSYCHOLOGICAL ROLE CAN THE FOLLOW-UP VISIT PLAY?

Although general support and reassurance after an abortion may be appreciated by some women, studies show that most adult women who terminate a pregnancy do not experience mental health problems^a.

Indeed, according to the American Psychological Association “*there is no credible evidence that a single elective abortion of an unwanted pregnancy in and of itself causes mental health problems for adult women*”. Moreover, in adult women with unplanned pregnancy, “*the relative risk of mental health problems is no greater if they have a single elective first-trimester abortion or deliver that pregnancy*”^b.

Studies have shown that for most women stress levels fall after the abortion, since it is a solution to the stress caused by the unwanted pregnancy^{c,d}. **Women should, however, be provided with information about where they can seek advice and support after the abortion if they experience ongoing grief or sadness.**

Women with risk factors for psychological problems after abortion (including lack of social support, ambivalence about the abortion, and membership of a cultural/religious group that considers abortion to be morally wrong) should be identified prior to the abortion, and offered additional counselling after the procedure.

^a Major B, et al. Abortion and mental health. *Evaluating the evidence. Am Psychol* 2009;64(9), 863–90.

^b American Psychological Association. APA Task Force finds abortion not a threat to women’s mental health. 2008 August 12 (<http://www.apa.org/news/press/releases/2008/08/single-abortion.aspx>)

^c Alder NE, et al. Psychological factors in abortion: A review. *Am Psychol* 1992;47:1194-204.

^d Stotland NL. Psychosocial aspects of induced abortion. *Clin Obstet Gynecol* 1997;40:673.

HOW TO MANAGE FAILURE OF MEDICAL ABORTION?

HOW TO MANAGE CONTINUING PREGNANCY?

Medical abortion fails in approximately 1% to 3% of cases.

If the pregnancy is ongoing, mifepristone and misoprostol can be administered again or surgical termination can be conducted.

HOW TO MANAGE INCOMPLETE ABORTION?

Blood clots, thick endometrium or residual products of conception are common findings on ultrasound performed within a few weeks of medical abortion, and are not usually clinically relevant.

If bleeding is not troublesome or heavy, and there are no signs of infection, then expectant management (i.e., waiting for the residual tissue to be passed) can be adopted.

Alternatively, the woman may choose to have further medical treatment with a single dose of misoprostol (600 µg oral or 400 µg sublingual: success rate > 90%)^{a,b}. For missed abortion, an 800 µg vaginal or 600 µg sublingual dose can be administered^c.



Surgical evacuation of the uterus may be carried out **in case of heavy bleeding, at the woman's request or if there is evidence of infection.** In the latter case, antibiotic treatment should be initiated.

^a Neilson JP, et al. Medical treatments for incomplete miscarriage (less than 24 weeks). *Cochrane Database Syst Rev.* 2010;(1):CD007223.

^b Neilson JP, et al. Medical treatment for early fetal death (less than 24 weeks). *Cochrane Database Syst Rev.* 2006;(3):CD002253.

^c Gemzell-Danielsson K, et al. Misoprostol to treat missed abortion in the first trimester. *Int J Gynaecol Obstet* 2007;99:S182–5.

IS THERE A RISK OF FOETAL ABNORMALITY AFTER UNSUCCESSFUL MEDICAL ABORTION?

In rare cases, the woman may change her mind and wish to continue her pregnancy after the start of the treatment or in case of an ongoing pregnancy found at follow-up. **Currently, the scientific literature does not allow the risk of foetal malformation after an unsuccessful medical abortion to be quantified, due to lack of data.**

Mifepristone has no teratogen effects in animals except on rabbits where isolated cases of severe abnormality have occurred. Misoprostol, which is sometimes used alone for abortion without medical supervision in some countries, or to treat gastric and duodenal ulcers, is suspected of inducing malformation, including cranial nerve defects^a.

In humans, 23 cases of congenital malformation out of 318 cases of continuing pregnancy were reported between 1987 and February 2012: 5 after mifepristone alone and 18 after mifepristone plus prostaglandin (misoprostol: 11 cases; gemeprost: 7 cases)^b. The incidence of birth defects in a normal population is around 2%-4% of births. The total number of medical abortions during the same period was estimated to be > 3,500,000. The foetal abnormalities reported with mifepristone alone and mifepristone plus prostaglandin were similar: limb defects, club foot, central nervous system anomalies and anomalies involving the palate but no clear causal relationship could be established. However, results suggest that exposure to prostaglandins may have had a possible role in the outcome.



Accordingly, **the potential teratogenicity of the treatment must be discussed before medical abortion** and it must be emphasised that once administered successful abortion should be confirmed.

^a Anonymous. *Misoprostol and pregnancy: risk of malformations. Prescrire Int.* 2008;17(94):65-6.

^b Pharmacovigilance data (Exelgyn).

However, **if the woman does change her mind after a failure**, in the absence of obvious causal relationship between product intake and foetal abnormalities, **there is no evidence that would justify a medical indication for termination.**

The woman needs to be informed that:

- Detecting an ongoing pregnancy is important, because of the potential risk to the foetus associated with the medical abortion drugs.
- The rate of naturally occurring abnormalities that may lead to later miscarriage or non-viability is high.



If the pregnancy continues and the woman finally decides to continue with the pregnancy, antenatal monitoring with an extra ultrasound scan (and special attention to the limbs) should be recommended.

GOOD PRACTICE POINTS

1. **Verification of successful expulsion is mandatory after medical abortion.** This can be done:

- In the facility, using ultrasound or hCG testing, or
- At home, with low-sensitivity hCG urinary tests in combination with assessment of bleeding and the absence of pregnancy symptoms.

There is no need for further follow-up when successful abortion was confirmed in the facility at the time of misoprostol intake.

2. Women should be provided with verbal and written information about symptoms that may indicate a complication and that would necessitate urgent medical consultation, and also about symptoms suggestive of ongoing pregnancy.
3. Clinicians should be aware that, when ultrasound is carried out routinely after medical abortion, blood clots or thick endometrium are common findings. They are not an indication for evacuation of the uterus. **The decision to perform an evacuation of the uterus should only be undertaken on the basis of clinical signs or symptoms and NOT on ultrasound findings alone.**
4. Rather than attending a clinic for follow-up, it may be considered appropriate for women (depending on how far they live from the facility, and on their preference) to have telephone follow-up. This would enquire about post-abortion bleeding and pregnancy symptoms, and the results of a self-performed low-sensitivity urine pregnancy test.
5. **If medical abortion fails and the woman wishes to continue with an ongoing pregnancy,** she should be informed that **regular antenatal monitoring and repeated ultrasound scans** are important, because of the potential harmful effects on the foetus associated with the medical abortion drugs.
6. Contraception should not be delayed and should be commenced at the time of abortion, since fertility resumes immediately after medical abortion.

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ARE THERE SPECIFIC MEASURES TO APPLY IN CASE OF ...?

Q1. MULTIPLE PREGNANCY (CURRENT GESTATION)

The same medical abortion drug and dosage regimen can be used to treat multiple pregnancy.

Q2. PREVIOUS CAESAREAN SECTION(S)

The safety and efficacy of early medical abortion are unaffected by previous caesarean section(s) when conducted up to 9 weeks of amenorrhea. If the woman chooses medical abortion, it should be performed as usual. Cases of uterine rupture (rare) have only been reported at later stages.

Q3. UTERINE MALFORMATION (CONGENITAL OR ACQUIRED) OR PREVIOUS CERVICAL SURGERY

There is no evidence that these represent contraindications when medical abortion is conducted up to 9 weeks of amenorrhea. If the woman chooses medical abortion, it should be performed as recommended.

Q4. BREASTFEEDING WOMEN

In practice, in medical abortion, the dosage of mifepristone and misoprostol allows nursing to be safely continued without interruption. (For further information, please see: "What are the contraindications and precautions for use for medical abortion?", p. 56).

Q5. OBESITY

The same medical abortion drug and dosage regimen can be used in women who are obese.

If the woman chooses medical abortion up to 9 weeks of amenorrhea, it should be performed as recommended.

Q6. WOMEN WITH VERY LOW BODY WEIGHT

The same medical abortion drug and dosage regimen can be used in women who are underweight. Both products have very wide safety margins.

If the woman chooses medical abortion, it should be performed as usual.

Q7. ALLERGY TO GLUTEN, CHICKEN PROTEIN, MILK PROTEIN

There is no evidence of cross-allergies. If the woman chooses medical abortion, it should be performed as usual.

Q8. CONTROLLED ASTHMA

Mifepristone has antiglucocorticoid effects. The efficacy of long-term corticosteroid therapy, including inhaled corticosteroids in asthma patients, may therefore be diminished during the 3 to 4 days following intake of mifepristone. Asthma therapy should be adjusted: it is recommended to double the dose inhaled for 2 days before and 2 days after mifepristone intake^a.

Q9. HIGH PLATELET COUNT

Women with high platelet count can have medical abortion; however, the cause should be ascertained before treatment.

Determination of the cause should not delay treatment.

Q10. ANTICOAGULANT THERAPY

Anticoagulant therapy is not a contraindication to medical abortion; however, as bleeding is increased, medical abortion should be avoided in women under anti-coagulant therapy.

^a Summary of product characteristics (<http://www.ema.europa.eu>).

Q11. DIABETES

There is no evidence that a different dosage regimen is required in diabetes, whether insulin- or non-insulin dependent. If the woman chooses medical abortion, it should be performed as usual. However, insulin-dependent subjects need therapy adjustment due to the stress of the procedure.

Q12. CONTROLLED THYROID GLAND DISEASE

No interaction studies are available. Because treatment is limited (one dose of mifepristone and one dose of prostaglandin), it has in theory no effect on thyroid hormone.

If a woman with controlled thyroid gland disease chooses medical abortion, it should be performed as recommended.

Q13. EPILEPSY

Epilepsy is not a contraindication to medical abortion. Drug interactions with anti-epileptics are unknown. However, although specific drug or food interactions with mifepristone have not been studied, its metabolism by CYP 3A4 makes it possible that certain anticonvulsants (phenytoin, phenobarbital, carbamazepine) may induce mifepristone metabolism (lowering the serum level).

If the woman chooses medical abortion, it should be performed as recommended.

Q14. WOMEN TAKING DRUGS FOR PSYCHOLOGICAL/PSYCHIATRIC DISORDER

There is no pharmacological problem in carrying out medical abortion in women under treatment for psychological/psychiatric disorder, although no interaction studies have been conducted.

However, the process takes several days and the woman needs to comply with the complete process.

WHAT DO THE WOMEN WANT TO KNOW?

Q1. WHAT ARE THE ADVANTAGES OF MEDICAL ABORTION?

The major advantage of medical abortion is that the termination can be carried out very early in gestation and no surgery is necessary.

Q2. WHICH IS THE BEST METHOD? «WHICH WOULD YOU CHOOSE?»

There is no «best method», and also no worst method. All methods are highly effective and there is ample experience with all of them. The decision is yours, taken according to your own situation and preferences.

Q3. WHICH IS THE NATURAL METHOD?

Medical abortion is not a natural event; however, it may be perceived by many women as being «more natural» than surgery because the clinical presentation and course are indistinguishable from spontaneous abortion or miscarriage.

Q4. IS MEDICAL ABORTION SAFE AND CAN I STILL HAVE CHILDREN AFTERWARDS?

Both of the medical abortion drugs have been formally studied and are known to be safe. Possible complications, which are rare, are described in the patient information notice. Future fertility and childbearing are not affected.

Q5. ARE REPEATED ABORTIONS DANGEROUS?

To date, no prospective studies have investigated the effects of repeated medical abortion. However, there is currently no pathophysiological reason to believe that repeated medical abortion has any adverse effects on a woman's physical or psychological health. Contraception is the best way to prevent unwanted pregnancies.

Q6. IS ABORTION PAINFUL FOR THE EMBRYO?

There is no feeling and no perception of pain felt by a foetus at that stage of pregnancy.

Q7. I'M WORRIED THE TREATMENT WON'T WORK. CAN MEDICAL ABORTION FAIL?

Medical abortion has very high efficacy: > 95%. There are few other treatments in medicine with such a high efficacy.

On-going pregnancy occurs in only 1 in 100 cases.

Q8. I HAVE HAD A MEDICAL ABORTION, I WAS WORRIED THE TREATMENT WOULDN'T WORK AND I CARRIED OUT A PREGNANCY TEST TO BE REASSURED. MY PREGNANCY TEST IS POSITIVE: WHAT SHOULD I DO?

A positive test some days after abortion is normal. Most chemical tests for pregnancy look for the presence of the pregnancy hormone hCG in urine, and after abortion the hCG level decreases only slowly. Usually 4 to 6 weeks are required to have a negative hCG test.

Other signs or clinical symptoms that you may still be pregnant are:

- You have had little or no bleeding after the treatment (< 4 days)
- You still feel pregnant
- You have not had your next period as expected after treatment

This may indicate that the pregnancy is ongoing, and you should consult your abortion care professional immediately.

Q9. HOW LONG DO I HAVE TO BE OFF WORK/SCHOOL?

Frequently, there is heavy bleeding and pelvic pain for a few hours after taking the prostaglandin; we recommend women not to work during that time. Most women return to work or school the day after the procedure.

Q10. HOW LONG AFTER MEDICAL ABORTION CAN I RESUME SEXUAL INTERCOURSE?

As soon as you want, but there have been no studies of the question.

Q11. HOW LONG IS THE NEXT MENSTRUATION AFTER MEDICAL ABORTION?

Your body starts a new cycle immediately after medical abortion. Consequently, most women will ovulate 2 weeks later and have their next period in 4 weeks. After medical abortion, the next menstruation may be slightly heavier than normal.

Q12. HOW MUCH WILL I BLEED?

Heavy bleeding and passing clots is common in medical abortion during the first days. Afterwards, lighter bleeding is common for an average of 9 days. If the bleeding continues to be heavier than your usual menses for more than 5 days, consult your healthcare professional.

Q13. HOW WOULD I KNOW THAT I HAVE TO VISIT A HEALTHCARE PROFESSIONAL IF THERE'S A PROBLEM?

You will have to contact and possibly consult a healthcare professional in case of:

- Heavy bleeding (more than 2 or 3 pads used every hour for more than 2 or 3 hours)
- Prolonged heavy bleeding (heavier than your usual menses for more than 5 days)
- Severe abdominal pain after expulsion
- Sustained fever
- Abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhoea) more than 24 hours after taking misoprostol.

Q14. HOW PAINFUL IS IT? I'M AFRAID OF PAIN.

Medical abortion causes mild to very strong cramping throughout and after the termination process. Cramping is usually worse for about 4-8 hours after prostaglandin, while the pregnancy is terminating. Milder cramps may continue for several days to 2 weeks.

Fear of pain is understandable. Many women experience cramps and lower abdominal pain, usually after taking prostaglandin. But some women do not experience any pain.

Painkillers will be prescribed to you and you can take them immediately after the procedure.

If you do have pain, the available painkillers are highly effective. You can also choose surgical abortion under anaesthesia.

Q15. WILL I SEE THE FOETUS?

It is NOT a foetus as this stage. The product of conception expelled is a gestational sac, which is white and looks like a small piece of sponge. From 7 weeks onwards, a small embryo might be visible inside the sac. Depending on the gestational age, you will not see any recognisable shape (up to 6.5 weeks of amenorrhea) or an embryo up to 2 cm at 9 weeks of amenorrhea.

- During ultrasound: You will see the scan only if you want to.
- During expulsion: It is possible that you will see a small white streak.

Q16. WHAT DO I NEED TO BRING TO THE HOSPITAL/ABORTION CENTRE WITH ME IF I HAVE A MEDICAL ABORTION?

- A card with your blood group, if available.
- Any prescribed medicines or inhalers that you take on a regular basis for any specific condition.

NB: Inform the centre of your medications and the reasons you are taking them.

- Stick-on sanitary towels
- Extra underwear.

Q17. HOW LONG DO THE CLINICAL SIGNS OF PREGNANCY LAST?

Usually nausea due to pregnancy disappears soon after medical abortion. Breast tenderness can continue for up to 3 weeks in some women.

Q18. CAN I USE TAMPONS DURING OR AFTER MEDICAL ABORTION?

During the first 2 days following medical abortion, you are advised not to use tampons, because there is a risk of infection.

Q19. CAN I TAKE SHOWERS AFTER MEDICAL ABORTION? CAN I HAVE A BATH?

You can take a shower at any time. During the first 2 days following medical abortion, it is preferable not to have a bath or to swim.

Q20. IS THERE A DIFFERENCE BETWEEN MEDICAL ABORTION AND EMERGENCY CONTRACEPTION (ALSO KNOWN AS THE «MORNING AFTER» PILL)?

Yes, medical abortion and emergency contraception are totally different. Medically, the beginning of pregnancy is defined as the implantation of a fertilised egg in the lining of the uterus. This begins 5 to 7 days after fertilisation and is complete several days later.

Emergency contraceptives work **before** fertilisation takes place and prevents ovulation. If a woman takes emergency contraception when she is already pregnant, it will not make any difference to the pregnancy and will not induce abortion.

Q21. WHY MUST I START CONTRACEPTION IMMEDIATELY AFTER ABORTION?

Your current pregnancy confirms that you are fertile. Abortion has no impact on your fertility. Most women are fertile immediately after the abortion. The risk of pregnancy is just the same after abortion. Contraception is the best method to avoid unwanted pregnancy.

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EARLY MEDICAL TERMINATION OF PREGNANCY – A PRACTICAL GUIDE FOR HEALTHCARE PROFESSIONALS

This practical guide is meant for all those professionals involved in medical abortion gynaecologists, physicians, midwives, nurses, social workers, etc.

This guide comprises the following chapters:

- “Introduction” on European legislations
- “Counselling”
- “Pre-abortion care”
- “Medical abortion treatment”
- “Post-abortion care”.

Tables, figures, boxes, conclusions and expert advice sections make for easy reading and a field book for everyday use.

The authors, Christian FIALA, Sharon CAMERON, Teresa-Alexandra CARMO-BOMBAS, Kristina GEMZELL-DANIELSSON, Mirella PARACHINI, Raha SHOJAI and Régine SITRUK-WARE, are gynaecologists/obstetricians or reproductive endocrinologists. They work in the field of family planning or abortion in their country (Austria, UK, Portugal, Sweden, Italy, France and USA, respectively). They are all members of the International Federation of Professional Abortion and Contraception Associates (FIAPAC). With this practical guide they want to help all those involved in abortion to perform medical abortion effectively and safely, with full respect for the woman who one day has experienced an unscheduled and unwanted pregnancy and requests help to stop her pregnancy.

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