

Patient agreement to investigation or treatment

Medical management of pregnancy of unknown location using Methotrexate

Authors: Gynaecology Department

Brief description:

- This leaflet aims to help you understand more about ectopic pregnancy generally and specifically about **medical management of a pregnancy of unknown location** using the drug **Methotrexate**. It also aims to tell you where to seek more support to help you to come to terms with losing your baby, and about planning future pregnancies.
- Here, we explain some of the aims, benefits, risks and alternatives to this procedure. We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website:
<http://www.cuh.org.uk/consent>
- Guidance for health professionals can be found on the Addenbrooke’s intranet site
<http://nww.addenbrookes.nhs.uk/consent>
- Remember, you can change your mind about having the procedure at any time even after you have signed the form.

For staff use:

Does the patient have any special requirements? (For example: requires an interpreter or other additional communication method)

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About medical management of pregnancy of unknown location using Methotrexate

After investigations, including blood tests and most probably an ultrasound scan too, your pregnancy is sadly unlikely to develop normally.

Unfortunately because of the inconclusive nature of some of the investigations, and your clinical history, we are unable to tell you if the pregnancy is in your womb or an ectopic pregnancy; (a pregnancy that develops outside the womb). This leads us to conclude that the location of your pregnancy is 'unknown'.

What we do know, is that your pregnancy hormone levels suggest that some form of treatment is required.

We are very sorry that this has happened, and hope that the information in this leaflet will be of some help to you and your partner.

The staff on Daphne ward hope to help you through this distressing time by:

- Explaining more about ectopic pregnancy.
- Explaining the treatment advised for you by the medical staff.
- Being available to give you advice over the telephone. When the unit is closed the main gynaecology ward, is available for you to contact. Contact telephone numbers are found further on in this leaflet.

Providing written information for you, in the form of this leaflet, to help you understand what is happening to you.

Frequently asked questions

What is an ectopic pregnancy?

Ectopic pregnancy is a common, potentially life-threatening, condition affecting one in 100 pregnancies. It occurs when the fertilised egg implants outside the cavity of the womb, usually the fallopian tube, and as the pregnancy grows it causes pain and bleeding. If it is not treated quickly enough, it can rupture the tube and cause abdominal bleeding, which can lead to shock and even death.

An ectopic pregnancy unlikely to develop normally and is consequently termed a type of miscarriage.

How is an ectopic pregnancy diagnosed?

The diagnosis is usually by a combination of tests such as blood beta-hCG (pregnancy hormone) tests and transvaginal ultrasound scan. This type of scan is used because it provides a better view of the womb, ovaries and fallopian tubes in early pregnancy. It involves inserting an ultrasound probe into the vagina. However, it is not always possible to see an ectopic pregnancy on scan.

During your scan no pregnancy can be seen in the womb where it can develop normally. In such circumstances it is usual that the scan will show an area outside of the womb that will indicate where the pregnancy is. In your case we can see neither but your hormone level indicates that something should be seen in either the womb or the fallopian tube and as it cannot be found we use the term “pregnancy of unknown location”.

What causes an ectopic pregnancy?

Normally a fertilised egg travels from the ovary down the fallopian tube, where it implants in the womb, usually six to seven days after fertilisation and there the pregnancy will develop. In an ectopic pregnancy the egg does not travel to the womb and can implant outside the womb, usually in the fallopian tube and does not develop properly. Pregnancies that cannot be located do not usually develop normally...

The most common cause of an ectopic pregnancy is damage to the fallopian tube, causing a blockage or narrowing. However, in most cases the cause of an ectopic pregnancy or pregnancy of unknown location is not known.

What are the symptoms of an ectopic pregnancy or pregnancy of unknown location?

These are often difficult to distinguish, making an ectopic pregnancy or pregnancy of unknown location very difficult to diagnose:

- A missed or delayed period.
- Usually a positive urine pregnancy test.
- Abdominal/ pelvic pain - this can be persistent and severe. It may be on one-side, but not necessarily on the side where the ectopic is.
- Shoulder-tip pain.
- Abnormal bleeding - this may be lighter or heavier than a normal period, and more prolonged. This bleeding is often dark in colour and watery (similar to prune juice).
- Diarrhoea or sometimes pain when opening the bowels.
- Fainting-feeling dizzy or light-headed.

Who is at risk of an ectopic pregnancy?

Any sexually active woman of child-bearing age is at risk of an ectopic, but the following factors are more commonly seen in women who have one:

- History of pelvic inflammatory disease, such as Chlamydia.
- Any previous abdominal surgery, such as appendectomy.
- Intra Uterine Contraceptive Device (IUCD) (Coil).
- The progesterone-only contraceptive pill (mini pill).
- In Vitro Fertilisation pregnancy.
- Previous ectopic pregnancy.
- Smoking.

Methotrexate

What is Methotrexate?

It is from the family of cytotoxic drugs. It works by preventing the placental cells from developing, leading to the pregnancy being absorbed. As only a small dosage is required, this also means that any side effects are lessened. However, in some instances depending on how your body responds to treatment you may require a second dose or, rarely, an operation.

Why have I been offered this treatment?

On the basis of your tests we think that your problem is unlikely to resolve without further treatment. We do, however, think it is likely that you will respond to this particular form of treatment.

During the procedure itself

How is the drug given?

It is administered by a suitably trained nurse into the large muscle of the buttock or thigh.

Each patient's dose is individually calculated and mixed by the Pharmacy Department, and this does take a few hours. Depending on your individual circumstances you may be admitted to the main Gynaecology Ward overnight, or you might be asked to return the following day to Daphne Ward to have the drug.

Provided you are feeling well, you will be allowed home shortly after administration of the drug.

Some patients (14%) require a further dose of the drug, and this would be similarly administered.

After the procedure

Is there anything I must avoid for the duration of my treatment?

Yes.

It is important you avoid the following:

- Sexual intercourse.
- Smoking.
- Alcohol.
- Folic acid.
- Exposure to the sun/sunlamps.

- Non steroidal anti inflammatory analgesia (NSAIDs) such as aspirin, ibuprofen, diclofenac.
- Herbal remedies.
- We would also advise you to take an adequate fluid intake avoiding dehydration during this procedure.

How many times will I have to return to the hospital for blood tests?

This varies for every woman, but certainly we will monitor your blood tests until the pregnancy hormone (Beta- β hCG) is negative. This usually takes anywhere between two to six weeks. Initially you will need to attend the hospital for repeat blood tests day four and seven after the methotrexate was given to you.

It is essential that we monitor you closely during this procedure and will not administer any treatment unless you commit to attending follow up appointments.

Will I experience any pain?

Yes, you might have some lower pelvic pain or back ache at any time during the course of your treatment. If required you can take paracetamol.

Whilst you are at home it is important to notify either Daphne Ward or Ward M4 if:

- you experience any increase in pain
- pain somewhere you have not previously had it
- you feel faint or dizzy
- paracetamol is insufficient for any pain you are experiencing

We understand that sometimes it can be frightening being at home during a course of treatment. Please do not hesitate to contact us on the numbers further on in this leaflet if you are unsure what do.

Will I have any vaginal bleeding?

Yes. This can vary from dark brown spotting to heavier bright red loss.

Use sanitary towels rather than tampons whilst you are bleeding, to reduce the risk of any infection.

If you are concerned that the bleeding is excessive (requiring you to change a sanitary pad every half an hour) please telephone either **Daphne ward** or **ward M4** for advice

Can I have a bath/shower during my treatment?

Avoid hot baths whilst you are bleeding heavily, as you may feel faint. Otherwise it is safe for you to have a warm bath or shower.

Should I be off work during the treatment?

This is a very individual thing. However, it is stressful having treatment, also you are recovering from the loss of your baby which can be a very distressing event in a woman's life.

Many women feel that at least a few days off work may be necessary, especially during the first week when frequent trips to the hospital are required.

You can self-certificate for the first week off work, alternatively the staff on Daphne Ward will provide you with a sick certificate.

How long must I wait before trying to become pregnant again?

At least three months. This ensures that all of the Methotrexate has left your body with no effect on future pregnancies.

During this time it is advisable to use condoms for contraception.

When can I expect a period?

Every woman is different regarding how soon after treatment for a pregnancy of unknown location they have their next period. However, sometime in the next four to six weeks is considered usual.

Often this period may be different than usual (heavier or lighter), again this is nothing to be concerned about, unless the bleeding is very heavy, in which case consult your GP or contact Daphne Ward directly.

What are the advantages of Methotrexate?

- It has a good success rate for treating small ectopic pregnancies (more than 90%).
- Avoids surgery and the associated risks of having a general anaesthetic.
- We can not guarantee to locate the pregnancy even if a diagnostic laparoscopy is carried out.
- It is less likely than surgery to cause further fallopian tube damage.
- It offers the best chance of maintaining fertility after treatment.
- You do not have to stay in hospital.

What are the disadvantages of Methotrexate?

- It can take a few weeks to complete the treatment.
- Side effects of the drug itself, such as: nausea, vomiting, diarrhoea.
- There may be some mild, temporary, abnormalities in liver function blood tests which you are unlikely to be aware of. However, you may require further blood tests during your treatment.

- Repeated visits to the hospital are essential (with blood tests).
- You may require a second dose of the drug.
- You are advised to wait at least three months before trying for a future pregnancy.
- You are more vulnerable to infection (if you come into contact with someone with flu/common cold etc).

Information and support

What happens when I do become pregnant again?

If you suspect you may be pregnant:

- Do an early urine pregnancy test at home.
- Contact Daphne Ward/ M4 Ward if you have any signs or symptoms similar to those you experienced on this occasion.

If you are otherwise well, your GP will arrange for you to have an early ultrasound scan, to ensure the pregnancy is in the womb.

How will I feel emotionally?

It is not unusual to feel low in mood or tearful at any time during or after a miscarriage, and this is true for women who have ectopic pregnancies too. Some women even feel quite angry, 'why has it happened to me?'

It is quite normal for you to feel sad and upset about losing your baby. Losing a baby can be a very painful experience for partners too, and sometimes their grief is unacknowledged.

If you feel that you, or your partner, need more help coming to terms with losing your baby, here are some contact numbers, which may be of use:

- The Ectopic Pregnancy Trust: 01895 238025 www.ectopicpregnancy.org.uk
- The Miscarriage Association (local contact Janet Sackman): 01763 249243 www.miscarriageassociation.org.uk

Do I need to inform anyone about my pregnancy loss?

No. Staff on Daphne Ward will have written to your GP & community midwife and any antenatal scans or appointments will have been cancelled, so you do not need to worry about doing this.

The future

Any preconception care you have been following should continue, once it is safe for you to try and become pregnant again such as:

- taking folic acid
- reducing your alcohol and caffeine intake
- ceasing smoking

If you are unsure whether you wish to try for a future pregnancy, it is advisable to consider your contraceptive needs during this time.

We hope this information has been of help to you. If you have any further concerns, please contact the staff on Daphne Ward.

Contact telephone numbers

- Daphne ward - 01223 217636
 - 08:00 until 20:00, Monday to Friday
 - 08:30 – 14:00 Saturday and Sunday
 - Closed Bank Holidays
- Ward M4 – 01223 348544
All other times

References/ Sources of evidence

- Royal College of Obstetricians and Gynaecologists (2004 reviewed 2010) *Guideline No.21: The management of Tubal Pregnancy*. RCOG London
- Royal College of Obstetricians and Gynaecologists (2010) *An Ectopic Pregnancy: Information for you*. RCOG London



We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas.

For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169

Help with this leaflet:



If you would like this information in another language, large print or audio format, please ask the department to contact Patient Information: 01223 216032 or patient.information@addenbrookes.nhs.uk



Document history

Authors	Gynaecology Department
Department	Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ www.cuh.org.uk
Contact number	01223 217636 /217755
Publish/Review date	October 2011/October 2014
File name	Medica_management_of_pregnancy_of_unknown_location_using_methotrexate
Version number/Ref	1/CF432

Consent form 1

Patient agreement to investigation or treatment

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Responsible health professional/job title

Special requirements
(For example, other language/other communication method)

Name of proposed procedure or course of treatment

Medical management of Pregnancy of Unknown Location using Methotrexate

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have explained the procedure to the patient. In particular, I have explained:

- The intended benefits of the procedure: High success rate at treating pregnancy of unknown location. To avoid surgery and is less likely than surgery to cause further fallopian tube damage. Maintaining fertility following treatment.
- Any serious or frequently occurring risks from the procedures including those specific to the patient: Potentially may require a second dose or possibly surgical intervention.
- Any extra procedures that might become necessary during the procedure

Blood transfusion Other procedure (please specify)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

- The following information leaflet has been provided:
..... Version/Date/Ref: 1/October 2011/CF432

This procedure will involve:

General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature: Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand:

Interpreter's signature..... Date:

Name (PRINT):

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will

Copy accepted by patient: yes / no (please circle)

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. **Yes** **No**

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** **If you wish** to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature: **Date:**

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature: **Date:**

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature **Date:**

Name (PRINT): **Job Title:**