Patient information and consent to medical management of an ectopic pregnancy using methotrexate

Key messages for patients

- Please read this information carefully, you and your health professional will sign it to document your consent.

- It is important that you bring the consent form with you when you attend for the injection. You will have an opportunity to ask any questions from the EPU staff when you are admitted. You may sign the consent form either before you come or when you are seen.

- Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- Simple painkillers such as paracetamol may be required after the injection.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- Please call clinic 24 (EPU) on telephone number 01223 217636 if you have any questions or concerns about this procedure or your appointment.

After the procedure we will scan the consent form into your electronic medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so).

We will also only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 2018.
About medical management of an ectopic pregnancy using methotrexate

Sadly your pregnancy has resulted in an ectopic pregnancy; this is a pregnancy that has developed outside the uterus (womb). 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 in clinic 24 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 clinic is closed, Daphne ward, the main Gynaecology Inpatient 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 uterus, 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 is unlikely to develop normally and is consequently termed a type of miscarriage.

What causes an ectopic pregnancy?

Normally a fertilised egg travels from the ovary down the fallopian tube, where it implants in the uterus, usually six to seven days after fertilisation and there the pregnancy will develop. In an ectopic pregnancy the egg does not travel to the uterus and can implant outside the uterus usually in the fallopian tube and does not develop properly.
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 is not known.

What are the symptoms of an ectopic pregnancy?
These are often difficult to distinguish, making an ectopic pregnancy very difficult to diagnose:

- A missed or delayed period.
- 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 pain.
- Abnormal bleeding – this may be lighter or heavier than a normal period, and last longer. 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 with an ectopic pregnancy who have had:

- 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 (POP/mini pill).
- In vitro fertilisation (IVF) pregnancy.
- History of a previous ectopic pregnancy.
- Smoking.
- Over 40 years of age.
- Breast feeding.

How is an ectopic pregnancy diagnosed?
Usually an ectopic pregnancy is diagnosed by a transvaginal ultrasound scan. This type of scan is used because it provides a better view of the uterus, ovaries and fallopian tubes. It involves inserting an ultrasound probe into the vagina. However, it is not always possible to see an ectopic pregnancy on scan.

If you are clinically well, you may have also required some blood tests (βhCG) over a 48 hour period to help with the diagnosis.
Methotrexate

What is methotrexate?
Methotrexate is a drug from the family of cytotoxic drugs. In your case it works by preventing the placental cells from developing, consequently only a small dosage is required, which 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?
Although the incidence of ectopic pregnancy may be increasing, undoubtedly more cases are diagnosed nowadays because of improved diagnostic facilities such as ultrasound and hormone blood tests which can be undertaken much earlier in the pregnancy. In the past many of these ectopic pregnancies may have resolved spontaneously and unknown.

On the basis of your tests we think this is unlikely to happen in your case. However, we do think it is likely that you will respond to this treatment, rather than surgery which may mean the removal of a fallopian tube.

Intended benefits
If your ectopic pregnancy is not too far advanced, or ruptured, it is an appropriate treatment option because:

- 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.
- 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.

Who will perform my procedure?
This treatment will be performed by a suitably trained nurse.

Before your procedure
You will have met the staff in clinic 24 who will ask for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the treatment, and feel free to discuss any concerns you might have at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring all your medications and any packaging (if available) with you.
How is the drug given?

The decision to offer you methotrexate is made by a consultant gynaecologist with the injection being 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 cytotoxic pharmacy department, and this does take a few hours. Depending on your individual circumstances you may be admitted to Daphne Ward overnight, or you might be asked to return the following day to clinic 24 to have the drug administered.

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

After the Injection

**Eating and drinking.** With the exception of avoiding alcohol and drinking plenty of fluids to prevent dehydration there are no restrictions to your eating and drinking.

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

**Resuming normal activities including work.** This is a very individual thing. However it is stressful having treatment, also you are recovering from the loss of your pregnancy 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 in clinic 24 will provide you with a “Fitness for work” certificate.

**Special measures after the procedure:**

It is important you avoid the following during the course of treatment:

- Sexual intercourse.
- Smoking.
- Alcohol.
- Folic acid.
- Exposure to the sun/sunlamps.
- Non-steroidal anti-inflammatory analgesia (NSAIDs) such as Aspirin, Ibuprofen (Nurofen), Diclofenac (Voltarol).
- Antibiotics such as Trimethoprim, Co-trimoxazole and Tetracycline
- If you regularly take any medication such as medication for diabetes, gastric reflux or epilepsy please discuss this with the nursing and/or medical staff
- Herbal remedies, including some tea infusions.
Anti-D: Women whose blood group is rhesus negative will be given an injection of Anti-D at the same time as the methotrexate injection to protect future pregnancies from being affected by rhesus incompatibility.

Pain: 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 clinic 24 or Daphne Ward 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.

Vaginal Bleeding: You may have some vaginal bleeding which 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 clinic 24 or Daphne Ward for advice. You may also attend the Emergency Department (ED) at any time outside of clinic 24’s opening hours.

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.

You are advised to wait at least three months before trying for a future pregnancy. 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.

Check-ups and results:
We will monitor your blood tests until the pregnancy hormone (βhCG) is negative. This usually takes anywhere between two to six weeks. Initially, you will need to attend the clinic for repeat blood tests on day four and day seven after the methotrexate was given to you, the staff will give you exact details before you leave.

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

When can I expect a period?
Every woman is different regarding how soon after treatment for an ectopic pregnancy they have their next period. However, sometime in the four to six weeks following your negative βhCG 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 clinic 24 directly.
What happens when I do become pregnant again?
Women who have had an ectopic pregnancy are more at risk of it happening again. If you suspect you may be pregnant:

- Do an early urine pregnancy test at home
- Contact clinic 24 or Daphne Ward if you have any signs or symptoms similar to those you experienced on this occasion.

If you are otherwise well, you or your GP can arrange for you to have an early ultrasound scan at your nearest EPU once you are at least seven weeks pregnant, to ensure the pregnancy is in the uterus.

How will I feel emotionally?
It is not unusual to feel low in mood or tearful at any time during or after a pregnancy loss. 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 pregnancy, this 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 pregnancy, here are some contact numbers, which may be of use:

- The Ectopic Pregnancy Trust
  01895 238025
  www.ectopicpregnancy.org.uk
- The Miscarriage Association
  www.miscarriageassociation.org.uk
- Association of Early Pregnancy Units
  http://earlypregnancy.org.uk/index.asp
- Petals Charity
  0300 688 0068
  https://petalscharity.org/
- Royal College of Obstetricians and Gynaecologists
  Information for you: Ectopic Pregnancy (2016)

Do I need to inform anyone about my ectopic pregnancy?
No. The staff in clinic 24 will have written to your GP and 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
Stopping smoking.
Exercise regularly and maintain a healthy diet.

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

**Significant, unavoidable or frequently occurring risks of this procedure**

If you have a pre-existing medical condition, are obese, have significant pathology or have had previous surgery the quoted risks for serious or frequent complications will be increased.

The table below is designed to help you understand the risks associated with this type of surgery (based on the RCOG *Information for you: Understanding how risk is presented in healthcare (2015)*).

<table>
<thead>
<tr>
<th>Term</th>
<th>Equivalent numerical ratio</th>
<th>Colloquial equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>1/1 to 1/10</td>
<td>A person in family</td>
</tr>
<tr>
<td>Common</td>
<td>1/10 to 1/100</td>
<td>A person in street</td>
</tr>
<tr>
<td>Uncommon</td>
<td>1/100 to 1/1000</td>
<td>A person in village</td>
</tr>
<tr>
<td>Rare</td>
<td>1/1000 to 1/10 000</td>
<td>A person in small town</td>
</tr>
<tr>
<td>Very rare</td>
<td>Less than 1/10 000</td>
<td>A person in large town</td>
</tr>
</tbody>
</table>

**Serious risks include:**

- 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.
- You may require a second dose of the drug - 14:100 (common)
- Less than 1:10 women may still require surgery (uncommon)
- Tubal rupture requiring immediate surgery - 7:100 (uncommon)

**Frequent risks include:**

- Abdominal pain – 75:100 women (very common)
- Side effects of the drug itself, such as: nausea, vomiting, diarrhoea, conjunctivitis,
- Bone marrow suppressions meaning you are more vulnerable to infection (if you come into contact with someone with flu/common cold etc).
- 36:100 women will need some help to get pregnant again (very common).
- 7 to 10:100 will have another ectopic pregnancy (common).

**Additional information:**

- It can take a few weeks to complete the treatment.
- Repeated visits to the hospital are essential (with blood tests) and we cannot commence treatment until you commit to this follow up.
Alternative procedures that are available

Depending upon the location and size of the ectopic, the level of hormones and other factors you may be offered:

- Expectant management of an ectopic pregnancy
- Surgical management of an ectopic pregnancy

Information and support

We understand that sometimes it can be frightening being at home during a course of treatment. Please do not hesitate to contact us if you are unsure what to do:

- clinic 24
  08:00 – 20:00, Monday – Friday
  08:30 – 14:00 Saturday and Sunday
  Closed on Bank Holidays
  01223 217636

- Daphne Ward
  (all other times)
  01223 257206
Information about important questions on the consent form

1 Creutzfeldt Jakob Disease (‘CJD’)

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2 Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment; they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3 Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4 Use of Tissue

As a leading biomedical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
5 ReSPECT (Recommended Summary Plan for Emergency Care and Treatment)

It is Trust policy that before we commence any treatment plan we discuss your wishes in the unlikely event there is a complication/emergency resulting from the treatment. The ReSPECT process creates a personalised recommendation for your clinical care in emergency situations where you are not able to make decisions or express your wishes. This enables your health professional to make clinical decisions and to act in your best interests and for your benefit.

The conversation helps us to understand your priorities of care and use those to develop an agreed plan that records what types of care or treatment:

- you would want to be considered for in an emergency
- you would not want to receive
- would not work or be of overall benefit to you.

There is further information available at: ReSPECT - Easy read Patient Information

Privacy & dignity

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language or audio, please contact Interpreting services on telephone: 01223 256998, or email: interpreting@addenbrookes.nhs.uk For Large Print information please contact the patient information team: patient.information@addenbrookes.nhs.uk.
Medical management of ectopic pregnancy with methotrexate

- It avoids surgery and the associated risks of having a general anaesthetic.
- 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.
- It can take a few weeks to complete the treatment.
- Side effects of the drug itself, such as: nausea, vomiting, diarrhoea and conjunctivitis.
- Mild, temporary, abnormalities in liver function blood tests, which you are unlikely to be aware of. 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 more vulnerable to infection.

b) the possible risks involved. Addenbrooke's always ensures any risks are minimised. However all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient:

Addenbrooke's Hospital | Rosie Hospital

CF0433, Medical management of an ectopic pregnancy using methotrexate, v3
Medical management of an ectopic pregnancy using methotrexate

2 The following information leaflet has been provided:

Medical management of an ectopic pregnancy using methotrexate

Version, reference and date: Version 3, CF433, June 2019
or ☐ I have offered the patient information about the procedure but this has been declined.

3 This procedure will involve:
☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation ☐ None

Signed (Health professional): ............................................................ Date: D.D./M.M./Y.Y.Y.Y
Name (PRINT): .................................................................................. Time (24hr): H.H.:M.M
Designation: ...................................................................................... Contact/bleep no:

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional. ☐ Yes ☐ No

2 Photography, Audio or Visual Recording
a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment. ☐ Yes ☐ No

b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting. ☐ Yes ☐ No

3 Students in training
I agree to the involvement of medical and other students as part of their formal training. ☐ Yes ☐ No
Medical management of an ectopic pregnancy using methotrexate, CF0433, Version 3

June 2019

Medical management of ectopic pregnancy with methotrexate

4 Use of Tissue
a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research.

☐ Yes  ☐ No

b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records.

☐ Yes  ☐ No

I have listed below any procedures that I do not wish to be carried out without further discussion.

________________________________________________________________________

________________________________________________________________________

I have read and understood the Patient Information about this procedure and the above additional information. I agree to the procedure or treatment.

Signed (Patient): ________________________________ Date: D.D./M.M./Y.Y.Y.Y.

Name of patient (PRINT): ________________________________

If signing for a child or young person; delete if not applicable.
I confirm I am a person with parental responsibility for the patient named on this form.

Signed: ____________________________________________ Date: D.D./M.M./Y.Y.Y.Y.

Relationship to patient: ________________________________

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): ________________________________ Date: D.D./M.M./Y.Y.Y.Y.

Name of witness (PRINT): ________________________________

Address: _____________________________________________

________________________________________________________________________

________________________________________________________________________
Medical management of ectopic pregnancy with methotrexate

D Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance)
On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): .................................................. Date: ...D./D./M.M./Y.Y.Y.Y...

Name (PRINT): ................................................................. Job title: .................................................................

Please initial to confirm all sections have been completed: .................................................................

E Interpreter’s statement (if appropriate)

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

Signed (Interpreter): .......................................................... Date: ...D./D./M.M./Y.Y.Y.Y...

Name (PRINT): .................................................................

Or, please note the language line reference ID number: .................................................................

F Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): ................................................................. Date: ...D./D./M.M./Y.Y.Y.Y...

Signed (Health professional): .......................................................... Date: ...D./D./M.M./Y.Y.Y.Y...

Name (PRINT): ................................................................. Job title: .................................................................

For staff use only: 
Hospital number: 
Surname: 
First names: 
Date of birth: 
NHS no: ___/___/___ 
Use hospital identification label