Patient information and consent to medical management of persistent pregnancy of unknown location using methotrexate

Key messages for patients

- **Please read this information carefully**, you and your health professional will sign it to document your consent. Please bring this consent form with you to the hospital on the day of your treatment.

- **Please bring with you any medications you use and its packaging (including patches, creams, inhalers, insulin and herbal remedies)** and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- 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 on **01223 217636** if you have any questions or concerns.

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

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 as long as it is safe and practical to do so.

We will also only carry out the treatment 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/treatments 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/treatment. However the person undertaking the procedure/treatment will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.
Introduction

Sadly because of the inconclusive nature of the blood tests, ultrasound scans and your clinical history, we are unable to tell you if the pregnancy is in your uterus (womb) or is an ectopic pregnancy (a pregnancy that develops outside the uterus). As we are not able to locate the pregnancy we label your condition as ‘pregnancy of unknown location’. This is generally a temporary label as further scans and blood tests will show if you had biochemical pregnancy (a pregnancy which did not develop far enough to be seen on scan), a miscarriage or an ectopic pregnancy. In your case this has not happened and you have what is known as a ‘persistent pregnancy of unknown location’. This can happen in 8 -10% of all women attending for early pregnancy scans.

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 in clinic 24 hope to help you through this distressing time by:

- Explaining more about pregnancy of unknown location (PUL)
- 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 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.

About pregnancy of unknown location

Pregnancy of unknown location is a label for which there are generally three possible outcomes:

1) an early intrauterine pregnancy – this means the pregnancy is in the correct place but too small to see on scan
2) a miscarriage – this means the pregnancy has ended and the developing tissue has already passed out of the body as you may have been bleeding. However if this is your first scan then there is no way to be sure the pregnancy was in the uterus in the first place. To be safe we need to be sure that there is definitely not an ectopic pregnancy.
3) an ectopic pregnancy which is a common, potentially life–threatening, condition affecting 1 in 100 pregnancies. It occurs when the fertilised egg implants outside the cavity of the uterus, usually in the fallopian tube, and as the pregnancy grows it causes pain and bleeding. If not treated quickly enough, it can rupture the tube and cause abdominal bleeding, which can lead to shock and even death.
In your case we cannot make any of the three diagnoses above as your ultrasound scan still has not shown us the location of a developing or failing pregnancy and your blood tests have plateaued and not rising or falling as we would expect. Your condition is therefore known as a **persistent pregnancy of unknown location**.

This is a difficult time for many women as the grief of a pregnancy ending can feel prolonged. This is not our intention, but we do want you to be safe.

**What are the symptoms of a pregnancy of unknown location (PUL)?**

It is often difficult to distinguish between an ectopic pregnancy or PUL as the symptoms are similar:

- 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 & watery (similar to prune juice).
- Diarrhoea or sometimes pain when opening the bowels.
- Fainting-feeling dizzy or light-headed.

**Treatment**

On the basis of your tests we think that your problem is unlikely to resolve without further treatment. Because of the risk of your retaining pregnancy tissue and the risk of an ectopic pregnancy we recommend that you have definite treatment in the form of medical management using methotrexate. We think it is likely that you will respond to this particular form of treatment.

Your condition is not suitable for surgery as we do not know where the cells are that need removing.

**What is Methotrexate?**

Methotrexate 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.
Intended benefits

- It has a good success rate for treating small ectopic pregnancies (more than 90%).
- It is unlikely 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 treatment

You will have met the staff in clinic 24 who will have asked you for details of your medical history and carried out any necessary clinical examinations and investigations.

Please ask 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?

Methotrexate 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 Daphne Ward overnight, or you might be asked to return the following working day to clinic 24 to have the drug administered.

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

Resuming normal activities including work

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, diclofenac
- 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
- We would also advise you to take an adequate fluid intake avoiding dehydration during this procedure.

Return to work: 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 in clinic 24 will provide you with a “Fitness for work” certificate.

Special measures after the treatment:

Anti-D: Women whose blood group is rhesus negative will be given an injection of anti-D alongside 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 but particularly three to seven days following administration of the drug. 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 felt 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.

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 a barrier method, such as condoms, for contraception.

**Check-ups and results:**
We will monitor your blood tests until the pregnancy hormone (Beta-ßhCG) 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 and thereafter weekly.

**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.**

**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 clinic 24 directly.

**What happens when I do become pregnant again?**
Women who have had a persistent pregnancy of unknown location 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, your GP will arrange for you to have an early ultrasound scan once you have reached seven weeks. This is to check the pregnancy is in the uterus.

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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 a pregnancy of unknown location 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 a baby. It 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
  www.miscarriageassociation.org.uk
- Association of Early Pregnancy Units
  http://earlypregnancy.org.uk/index.asp
- Petals Charity
  0300 688 0068

Do I need to inform anyone about my pregnancy loss?

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
- 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.
Significant, unavoidable or frequently occurring risks of this procedure/treatment

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 Clinical Governance Advice, Presenting Information on Risk):

<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 1/10000</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 (very common)
- Less than 1:100 women may still require surgery (uncommon)
- Tubal rupture requiring immediate surgery- 7:100 (uncommon)

Frequent risks include:

- Abdominal pain – 75:100 women (common)
- Side effects of the drug itself, such as: nausea, vomiting, diarrhoea, conjunctivitis.
- Bone marrow suppression 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).

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 or treatments that are available

- One alternative to the treatment is to decide to do nothing. The ramifications of this will be discussed with you by your doctor/nurse.
- It may be that in your case surgery is not recommended as we may not find the pregnancy and have what is termed a ‘negative laparoscopy’. However if you become symptomatic at any time, that is have a lot of pain, you will be offered surgical management.
If you meet criteria you may be suitable for expectant management of PUL, this would involve your being monitored by blood tests and ultrasound scans.

**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 do:

**Contact telephone numbers**

- **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  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.

2  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.

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 now 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, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.information@addenbrookes.nhs.uk.
Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history

Authors  Lisa Prentice, Sandra Kent & Miriam Baumgarten
Department  Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ  www.cuh.org.uk
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Medical management of pregnancy of unknown location using methotrexate  CF432, Version 2, September 2015
Medical management of pregnancy of unknown location using methotrexate

It has a good success rate for treating small ectopic pregnancies (more than 90%). It is unlikely to cause further fallopian tube damage. It offers the best chance of maintaining fertility after treatment.

- It can take a few weeks to complete the treatment.
- Side effects of the drug itself, such as: nausea, vomiting, diarrhoea.
- 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.
- Wait at least three months before trying for a future pregnancy to ensure all of the Methotrexate has left your body with no effect on future pregnancies.
- 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

- It can take a few weeks to complete the treatment.
- Side effects of the drug itself, such as: nausea, vomiting, diarrhoea.
- 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.
- Wait at least three months before trying for a future pregnancy to ensure all of the Methotrexate has left your body with no effect on future pregnancies.
- You are more vulnerable to infection

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
Medical management of pregnancy of unknown location using methotrexate

d) any extra procedures that might become necessary during the procedure such as:
   - Blood transfusion
   - Other procedure (please state)

2 The following information leaflet has been provided:

   Medical management of pregnancy of unknown location using methotrexate

   Version, reference and date: CF432 version 2 September 2015
   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

Patient safety – at the heart of all we do

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CF432 version 2, Approved September 2015
Medical management of pregnancy of unknown location using methotrexate

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

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

Signed (Patient): .......................................................... Date: __/__/____
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: __/__/____
Relationship to patient:

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.
Signed (Witness): .......................................................... Date: __/__/____
Name of witness (PRINT): ..........................................................
Address: ..........................................................
Consent Form

Medical management of pregnancy of unknown location using methotrexate

D Confirmation of consent

Confirmation of consent (where the procedure/treatment 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 procedure/treatment 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

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