Academic and Clinical Central Office for Research and Development

Patient Information Sheet

OSPREY

Exploratory study of a single dose of methotrexate for the treatment of a stable ectopic pregnancy

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others (family, friends or your doctor) about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

An ectopic pregnancy occurs when a fertilised egg attaches itself somewhere other than inside the womb, usually in a Fallopian tube. Sadly, there is no chance of an ectopic pregnancy developing into a healthy pregnancy and, if the ectopic pregnancy continues, it could potentially lead to bleeding inside the abdomen which can be a life-threatening situation for a woman.

If the ectopic pregnancy is detected early enough, it may be treated with a drug called methotrexate which stops the pregnancy developing. Methotrexate is sometimes given as a single dose, two doses, or multiple doses. How much methotrexate is administered (given) varies in different countries across the world and is based on research evidence from the 1980s. To decide on the dose amount(s), doctors perform a calculation based on an individual's weight or body surface area. Therefore, how much methotrexate is given will vary from patient to patient.

This study aims to see how acceptable a single injection of a standardised dose of methotrexate (100mg/ml) is for the medical treatment of ectopic pregnancy. This is not the highest dose that is given to patients but is higher than you would usually receive given your height and weight.

This is a small pilot study of 10 women to help us design a larger trial which would investigate the benefits of having a standardised ready-to-use dose of methotrexate available.

Why have I been invited to take part?

You are being asked to consider taking part because you have unfortunately been diagnosed with an ectopic pregnancy which is being treated with methotrexate. We require 10 women to take part in our trial.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive or your legal rights.

What will happen if I take part?

Once you have finished reading this information sheet, you will be given time to decide whether or not to take part. This may be less than 24 hours if you are receiving methotrexate treatment on the same day as you are given this information sheet. This is so that your treatment is not delayed.

We will ensure that you have time to discuss this study and your decision with your partner or family/friends and will answer any questions you may have.

If you decide to take part, you will be asked by a member of the research team to sign a consent form. With that consent, we will then look at your blood and ultrasound results to confirm that you are eligible to take part and will ask you some questions about your medical history. If a doctor confirms that you can take part in the trial, you will receive a single intramuscular (into a muscle) injection of methotrexate (100mg/ml).

You will have hospital appointments as is usual with this type of treatment and so there are no extra/additional hospital visits if you take part. The appointments involve blood tests to measure your pregnancy hormone (hCG) levels at around days 4, 7 and then weekly, until your pregnancy hormone level is back to a pre-pregnancy level. We will look at your medical notes to get your blood results and other clinical details.

If you feel unwell between visits, you should first contact the pregnancy support centre. You will be given these contact details during your first visit with them.

Are there any side effects or risks involved?

The most common side effects of a single injection of methotrexate for the treatment of ectopic pregnancy are: nausea, diarrhoea and skin rash. Other possible side effects include: vomiting, poor appetite, weight loss, acne, dry skin, mouth ulcers, itch and a feeling of listlessness (tiredness/fatigue). There are other side effects that can happen with methotrexate but these listed are most commonly seen in women having ectopic pregnancy treatment.

Allergic reactions can occur with any medication. If you experience any shortness of breath, wheezing, difficulty breathing, facial numbness, swelling or a rash, please notify a doctor as soon as possible. When you are given the methotrexate dose, you will be asked to stay in the hospital for about 30 minutes after your injection to make sure you have no immediate allergic reaction.

Is there anything I need to do or avoid?

The usual practice for anyone taking methotrexate alone for ectopic pregnancy is to avoid getting pregnant (use contraception) and not to breastfeed for at least three months after the injection.

What are the possible benefits of taking part?

You may not personally benefit from taking part in this study but the results might help to improve the healthcare of patients with ectopic pregnancy in the future.

What are the possible disadvantages of taking part?

There are no additional visits required as part of this study. We will require additional time to complete a questionnaire.

What if there are any problems?

If you have any concerns about any aspect of this study, please contact your clinical researchers at 07884 115330 or 07895 238 944 who will do their best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence (failure to take reasonable care), then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The usual National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study

You can withdraw from the study at any time without having to give a reason. With your permission, we will use any data obtained as a result of your participation. All data will be anonymised (have no names on it).

What happens when the study is finished?

Personal data will be stored for a minimum of 1 year. Selected anonymised collected or generated data by the study will be shared with Nordic Pharma who are funding the trial once the study is finished.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. All study data will be anonymised apart from the consent form and an ID log that we keep separate from all other trial paperwork so that you cannot be identified by anyone other than member of the research team. All data that we hold will be anonymised and you will not be able to be identified in any of the results.

How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your name, phone number, address and email as well as your Community Health Index (CHI) number which uniquely identifies you. Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Some information about you will be sent to Nordic Pharma (The Netherlands) who are funding the study. They must follow our rules about keeping your information safe. You cannot be identified through the information sent by us to Nordic Pharma.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep all information about you safe and secure.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at **www.hra.nhs.uk/information-about-patients/**
- our leaflet available from [**www.hra.nhs.uk/patientdataandresearch**]
- by asking one of the research team
- by sending an email to dpo@ed.ac.uk, or Lothian DPO@nhs.net
- by ringing us on 0131 651 4114 or 0131 465 5444

What will happen to the results of the study?

The results of this study will be published in medical journals, reports and textbooks. You will be able to see the results on the Ectopic Pregnancy Trust website and on Professor Horne's website (https://www.ed.ac.uk/centre-reproductive-health/professor-andrew-horne). You will not be identifiable in any publication or report. Nordic Pharma will have access to the anonymised results of this study.

Who is organising and funding the research?

This study has been organised by Professor Andrew Horne and sponsored by University of Edinburgh/NHS Lothian.

The study is being funded by Nordic Pharma.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from HSC REC A and NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study please contact:
Ann Doust
University of Edinburgh
Room S7128
2nd Floor Simpson Centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
EH16 4SA
Tel: 07810643488

Email: ann.doust@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Dr Jackie Maybin
The Queen's Medical Research Institute
Edinburgh BioQuarter
47 Little France Crescent
Edinburgh
EH16 4TJ

Tel: 0131 242 6240

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Complaints

If you wish to make a complaint about the study please contact the researcher, Ann Doust, details above or:

Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
feedback@nhslothian.scot.nhs.uk
0131 536 3370

Support

If you would like general information and someone to talk to about ectopic pregnancy and what you are going through, The Ectopic Pregnancy Trust can help. The EPT is a charity and so cannot provide personal medical advice but can offer peer-to-peer support. Please visit ectopic.org.uk.

Participant ID:

CONSENT FORM
OSPREY

Please **initial** box

1. I confirm that I have read and understand the information sheet (18 Jun 2021 Version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
3. I give permission for the research team to access my medical records for the purposes of this research study. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. ☐
5. I give permission for my personal information (including name, address, date of birth, telephone number, email and consent form) to be kept by the University of Edinburgh for administration of the study. ☐
6. I give permission for my Community Health Index (CHI) number/hospital number to be collected and passed to the University of Edinburgh. ☐
7. I agree to my General Practitioner being informed of my participation in the study. ☐
8. I understand that data collected about me during the study will be converted to anonymised data. ☐
9. As with all research, it is possible that in the future it may have commercial applications. I understand that I will not benefit financially if this research leads to future treatment. I agree for my anonymised data to be shared with Nordic Pharmaceuticals, based in the Netherlands. ☐
10. I agree to take part in the OSPREY Trial. ☐

Name of Person Giving Consent	Date	Signature
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1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record