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A study to assess the safety of using 100 mg methotrexate for the treatment of an unruptured ectopic pregnancy

Submission date
23/10/2025

Recruitment status
No longer recruiting

Registration date
28/11/2025

Overall study status
Completed

Last Edited
10/12/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We will explore the feasibility of giving women who have a stable, ectopic pregnancy (a pregnancy that has implanted in the Fallopian tube and not the uterus) a single dose of methotrexate of 100 mg/ml. Methotrexate is a drug used to treat ectopic pregnancies and is usual standard care when a patient presents in a stable condition. The dose is calculated depending on the patient's body surface area (calculated using height and weight). The differing doses then have to be prepared in pharmacies (these range between 60 and 120 mg). This adds to waiting times and burden on patients. The aim of this study is to find out whether we can safely give all women a standard dose.

Who can participate?
Women aged between 18-45 years who have a stable ectopic pregnancy

What does the study involve?
Participants are given a standard one-off dose of methotrexate of 100 mg/ml. All of the women recruited to the study would normally have received less than 100 mg of methotrexate had they received standard care. We will follow them up as per usual clinical care (no extra visits) until the pregnancy resolves. We will look at side effects experienced by these women and compare these to side effects experienced by the women who are given a slightly lower dose (published historical data).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study will be carried out at the Pregnancy Support Centre within the Royal Infirmary of Edinburgh, NHS Lothian (UK)

When is the study starting and how long is it expected to run for?
November 2020 to June 2023

Who is funding the study?
Nordic Pharma Group

Who is the main contact?
Ann Doust, ann.doust@ed.ac.uk

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2020-004592-40

Integrated Research Application System (IRAS)
285725

Central Portfolio Management System (CPMS)
49625

Study information

Scientific Title
OSPREY: An open-label exploratory study to assess the safety of using 100 mg of methotrexate as a standard dose treatment for women with unruptured ectopic pregnancy

Acronym
OSPREY

Study objectives
To explore the safety of 100 mg/ml dose of MTX in patients who routinely would receive 85 mg or lower based on their body surface area.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/11/2020, Health & Social Care Research Ethics Committee A (HSC REC A) (Office for Research Ethics Committees Northern Ireland (ORECNI) Customer Care & Performance Directorate Lissue Industrial Estate West 5 Rathdown Walk Moira Road, Lisburn, BT28 2RF, United Kingdom; +44 (0)28 95361407; RECA@hscni.net), ref: 20/NI/0136

Study design
Single-site open-label exploratory study

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Ectopic pregnancy

Interventions
Osprey is a single-site open-label exploratory study of the safety and outcomes of using a pre-prepared single dose of 100 mg/ml MTX given via an IM injection in women with a stable EP.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Methotrexate

Primary outcome(s)
Safety endpoint:
1. Incidence of related adverse events measured from baseline until resolution of ectopic pregnancy
2. Changes to blood haemotological, renal and liver function tests measured at baseline, day 4 and day 7 post treatment

Key secondary outcome(s))
1. Time to resolution of ectopic pregnancy (number of days from treatment with methotrexate until serum hCG)
2. Treatment failure (requirement for second injection of methotrexate or requirement for surgical intervention)

Timelines for both measures were variable across participants

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Clinical decision made for treatment with MTX
2. Women aged between 18-45 years
3. Serum hCG >15 IU/l
4. Diagnosis of an ectopic pregnancy/pregnancy of unknown location
5. Body surface area ≤1.75 m2 but ≥1.25 m2
6. Haemoglobin between 100 and 165g/l within 3 days of treatment
7. Clinically stable e.g. no abdominal guarding or rigidity on examination and no evidence significant of intra-abdominal bleeding on USS
8. Able to understand all information and provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Total final enrolment
10

Key exclusion criteria
1. Clinically significant abnormal haematological/renal/liver indices noted on pre-treatment blood test (within 3 days of treatment)
2. Significant abdominal pain
3. Evidence of intrauterine pregnancy
4. Evidence of significant intra-abdominal bleed on USS defined by echogenic free fluid above the uterine fundus or surrounding ovary within 1 day of treatment
5. EP mass on USS of greater than 3.5 cm (mean dimensions) which is deemed not suitable for treatment with MTX
6. Currently breastfeeding and unwilling to stop

Date of first enrolment
26/07/2021

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

Sponsor information

Organisation
Accord (United Kingdom)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Industry

Funder Name
Nordic Pharma Group

Alternative Name(s)
Nordic Group, Nordic Pharma

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
France

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		10/12/2025	10/12/2025	No	No
Participant information sheet	version 3	18/06/2021	28/10/2025	No	Yes

Protocol file	version 2	17/06/2021	28/10/2025	No		No