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Randomised double blind controlled trial of single dose methotrexate versus expectant management in women with tubal ectopic pregnancy

Submission date
15/08/2005

Recruitment status
No longer recruiting

Registration date
21/11/2005

Overall study status
Completed

Last Edited
16/03/2017

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
It is not known whether methotrexate is needed to treat ectopic pregnancies (when a fertilised egg implants itself outside of the womb) with relatively low hormone levels. This study aims to see whether patients need methotrexate or whether these ectopic pregnancies get better without any treatment.

Who can participate?
Women with mild symptoms, an ectopic pregnancy seen on ultrasound scan (without a heartbeat or internal bleeding) and a blood test showing human chorionic gonadotropin (hCG) hormone levels less than 1500 IU/l.

What does the study involve?
Participants will be randomly allocated to have an injection of either methotrexate or water (you will not know which you get and neither will your doctor), then will have their blood levels of hCG monitored to see if the ectopic pregnancy gets better.

What are the possible benefits and risks of participating?
The results of this study will help us to work out what is the best treatment strategy. The risks are the treatment may not work, whether you get the methotrexate or not, and this will means having an operation to remove the ectopic pregnancy.

Where is the study run from?
Kings College Hospital and University College Hospital, London (UK).

When is the study starting and how long is it expected to run for?
The study started in August 2005 and is expected to run until September 2014.

Who is funding the study?
Kings College Hospital Early Pregnancy Unit (UK).

Who is the main contact?
Jackie Ross
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Contact information

Type(s)
Scientific

Contact name
Ms Jackie Ross

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United Kingdom
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Additional identifiers

Study information

Scientific Title
Randomised double blind controlled trial of single dose methotrexate versus expectant management in women with tubal ectopic pregnancy

Study objectives
To assess the efficacy of methotrexate for the non-surgical management of tubal ectopic pregnancies.

On 06/07/2010, the anticipated end date was changed from 01/09/2007 to 01/09/2010. The trial has also been expanded to include University College Hospital and Leicester Royal Infirmary.

On 13/09/2013, the anticipated end date was changed from 01/09/2010 to 01/09/2014 and the target number of participants was changed from "50 women in each group gives 90% power to detect a difference" to "35 women in each group gives 80% power to detect a difference."

As of 05/06/2014 the study has completed recruitment and is in the data analysis phase.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the local research ethics committee in May 2005

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tubal ectopic pregnancy

Interventions
Women who fulfill the inclusion criteria and have normal blood results will be randomised to methotrexate treatment or placebo. Those having methotrexate will be given a single dose 50 mg/m^2. Women randomised to placebo will be given an injection of 1 ml of normal saline intra-muscularly. All women will be managed on an outpatient basis and attend for a serum hCG measurement in 96 hours. Provided patients are clinically stable they will attend for another blood test 72 hours later. The treatment failure will be defined as a rise in serum hCG greater than 15% on two consecutive measurements.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
The percentage of women successfully treated.

Key secondary outcome(s)
1. Complications such as tubal rupture, pain and the need for emergency surgery
2. Length of time followed up (i.e. time for beta-hCG to fall to below 20 IU/l)

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Certain ultrasound diagnosis of tubal ectopic pregnancy
2. Clinically stable patient with no evidence of haematoperitoneum on ultrasound scan
3. Non-viable pregnancy
4. No history of liver or renal disease

5. Normal red and white cell count, renal and liver function tests
6. Inital serum human Chorionic Gonadotropin (hCG) less than 1500 IU/l
7. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Haemodynamic instability
2. Severe pain
3. History renal/liver/pulmonary disease
4. Blood dyscrasia
5. Haematoperitoneum
6. Foetal heart present
7. Written informed consent declined

Date of first enrolment
15/08/2005

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Early Pregnancy and Gynaecology Assessment Unit
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Trust (UK)

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
King's College Hospital NHS Trust (UK) - Early Pregnancy and Gynaecology Assessment Unit

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2017		Yes	No