ISRCTN28090716 https://doi.org/10.1186/ISRCTN28090716

A randomised controlled trial of prednisolone for women with recurrent miscarriage and high levels of uterine natural killer cells in the endometrium

Submission date
05/07/2007

Recruitment status
No longer recruiting

Registration date
30/08/2007

Overall study status
Completed

Last Edited
08/01/2010

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LWH0606

Study information

Scientific Title

Acronym
Prednisolone study

Study objectives
Prednisolone therapy during the first trimester of pregnancy is able to reduce the chance of miscarriage compared to placebo in women with idiopathic recurrent miscarriage and raised uterine Natural Killer (uNK) cell numbers in their endometrium.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Liverpool Research Ethics Committee on the 9th November 2005 (ref: 05/Q1505/115).

Study design
Randomised double-blind, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Recurrent miscarriage

Interventions
Group one: these women will be allocated oral prednisolone, 20 mg a day for six weeks, then 10 mg for one week, then 5 mg for one week.
Group two: these women will be allocated oral placebo tablets with identical packaging and instructions to group one.

All women will have fortnightly monitoring of blood pressure and blood glucose, and for side effects. Women will be followed up throughout the course of their pregnancies.

Joint Sponsor details:
University of Liverpool (UK)
Research and Business Services
The Foresight Centre
3 Brownlow Street
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United Kingdom
Director of Research: Ian Carter
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Website: http://www.liverpool.ac.uk

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Live birth rate, this outcome will be measured in accordance with each woman's achieved gestation period.

Secondary outcome measures
1. Conception rate
2. First trimester losses
3. Second trimester miscarriages
4. Still births
5. Intrauterine growth restriction
6. Pre-eclampsia
7. Abruption
8. Gestation at delivery
9. Foetal abnormality
10. Side effects of steroids

Secondary outcomes will be measured during routine high risk antenatal clinic appointments (every 2 weeks up until 12 weeks gestation; 28 weeks and 34 weeks gestation). The women will be in regular contact with the Chief Investigator as and when they feel the need (if they have concerns) and during their routine clinic appointments - during which secondary outcomes will be reported.

Overall study start date
01/08/2007

Completion date
01/08/2013

Eligibility

Key inclusion criteria
1. Women with three or more consecutive idiopathic first trimester miscarriages and more than 5% of endometrial cells CD56+
2. Women aged between 20 and 40 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
68 women in each arm (136 total)

Key exclusion criteria
1. Known cause for pregnancy losses
2. Anti-phospholipid antibody syndrome
3. Parental balanced translocation, uterine anomaly
4. Known thrombophilia

Date of first enrolment
01/08/2007

Date of final enrolment
01/08/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Women's NHS Foundation Trust
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation

Liverpool Women's NHS Foundation Trust (UK)

Sponsor details
Crown Street
Liverpool
England
United Kingdom
L8 7SS
+44 (0)151 702 4346
lynne.webster@lwh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.lwh.org.uk/

ROR
https://ror.org/04q5r0746

Funder(s)

Funder type
Charity

Funder Name
Current sources of funding as of 19/08/2008:

Funder Name
Moulton Charitable Foundation (UK)

Funder Name
Previous sources of funding:

Funder Name
Liverpool Women's NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	10/11/2009		Yes	No