

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	☐ Prospectively registered
Registration date 30/08/2007	Overall study status Completed	☐ Protocol
Last Edited 08/01/2010	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ 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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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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

Liverpool, L69 3GL

United Kingdom

Director of Research: Ian Carter

E-mail: i.carter@liv.ac.uk

Website: <http://www.liverpool.ac.uk>

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Prednisolone

Primary outcome(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Study participating centre

Liverpool Women's NHS Foundation Trust

Liverpool

United Kingdom

L8 7SS

Sponsor information**Organisation**

Liverpool Women's NHS Foundation Trust (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

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