# The Scottish Pregnancy Intervention Study: The effect of low molecular weight heparin and aspirin therapy on recurrent pregnancy loss

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
23/08/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
16/09/2005	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
07/04/2010	Pregnancy and Childbirth	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Peter Clark

#### Contact details

Scottish National Blood Transfusion Service East of Scotland Blood Transfusion Centre Ninewells Hospital Dundee United Kingdom DD1 9SY

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** OBGYN SPIN 01

# Study information

#### Scientific Title

## Acronym

**SPIN** 

## Study objectives

Does treatment with low dose aspirin and Low Molecular Weight Heparin (LMWH) in women with consecutive recurrent pregnancy loss(es) at less than/equal to 24 weeks gestation (and no evidence of anatomical, endocrine, chromosomal or immunological abnormality) result in a reduction in the rate of expected loss in the index pregnancy from 25% to 15% or less?

Please note that as of 13/11/2007 the funding by the Chief Scientist Office was extended from 31/05/2007 to the 31/12/2008 for this trial. The end date of this trial has been changed to reflect this.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the North West Multicentre Research Ethics Committee (MREC) on the 30th September 2003 (ref: MREC 03/8/041)

## Study design

Randomised 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**

Low Molecular Weight Heparin, aspirin and intense surveillance versus intense surveillance only.

Medications given as follows: enoxaparin 40 mg subcutaneously, once per day by self injection and 75 mg aspirin orally once daily. Medications are prescribed at randomisation and stop at 36 weeks gestation.

## **Intervention Type**

Drug

## Phase

**Not Specified** 

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

Aspirin, low molecular weight heparin (LMWH)

## Primary outcome measure

Live birth rate (delivery of a live infant beyond 37 weeks of gestation).

## Secondary outcome measures

- 1. Preterm delivery of a live infant (between 28 and 37 weeks of gestation)
- 2. Obstetric complications (pregnancy associated hypertension, pre-eclampsia, intrauterine growth retardation)
- 3. Congenital malformations
- 4. Admission to special care
- 5. Side-effects of the drug used, both for the mother and the baby
- 6. Thromboembolic complications

## Overall study start date

01/06/2004

# Completion date

31/12/2008

# **Eligibility**

## Key inclusion criteria

- 1. Have a history of a minimum of two consecutive early pregnancy losses (defined as at/or before 24 weeks gestation)
- 2. Present at less than or equal to 7 weeks gestation with a positive pregnancy test and confirmatory ultrasound
- 3. Give written informed consent

## Participant type(s)

**Patient** 

## Age group

Adult

#### Sex

**Female** 

## Target number of participants

600

## Key exclusion criteria

- 1. A previous foetal loss has been associated with an anatomical, chromosomal, (maternal /paternal) endocrine or immunological cause
- 2. They have a previous history of venous or arterial thrombosis
- 3. They are already known to have antiphospholipid syndrome (as defined by the presence of an antiphospholipid antibody and three consecutive early pregnancy failures)
- 4. At enrolment are already known to have a thrombophilic disorder
- 5. They have a history of three or more pregnancy losses and are found or are already known to have a positive lupus inhibitor screen or Immunoglobulin G (IgG)/Immunoglobulin M (IgM) anticardiolipin antibodies above the local reference range
- 6. Are found to have an excluding condition on booking for the current pregnancy such as anaemia requiring therapy, platelets less than 150 x 10^12/l, abnormal thyroid function, multiple or rare red cell alloantibodies or auto-antibodies
- 7. Known hypersensitivity to the active substance or any of the excipients

## Date of first enrolment

01/06/2004

## Date of final enrolment

31/12/2008

# Locations

## Countries of recruitment

Scotland

United Kingdom

## Study participating centre Scottish National Blood Dundee United Kingdom DD1 9SY

# Sponsor information

## Organisation

Greater Glasgow Health Board (North Glasgow University Hospitals Division) and Glasgow University (UK)

## Sponsor details

Divisional Headquarters 300 Balgrayhill Road Glasgow Scotland United Kingdom G21 3UR

## Sponsor type

Hospital/treatment centre

## **ROR**

https://ror.org/05kdz4d87

# Funder(s)

# Funder type

Government

## Funder Name

Scottish Executive, Health Department, Chief Scientist Office (UK) (Ref: CZB/4/110)

# **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	27/05/2010		Yes	No