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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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