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Does heparin improve pregnancy outcomes for women with evidence of placental dysfunction?

Submission date 20/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/05/2007	**Overall study status** Completed	
Last Edited 28/09/2009	**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
N/A

Study information

Scientific Title
Does heparin improve pregnancy outcomes for women with evidence of placental dysfunction? A randomised controlled trial

Acronym
HEPRIN: HEparin for the PRevention of complications related to placental INsufficiency

Study objectives
The administration of heparin to women with identified placental dysfunction will:
1. Reduce the risk of intra-uterine foetal death
2. Reduce the risk of other adverse pregnancy outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Mount Sinai Hospital (Canada) on the 6th March 2007.

Study design
Randomised controlled open label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pregnancy; placental dysfunction

Interventions
Daily subcutaneous heparin (7500 units twice daily from randomisation [18 to 24 weeks gestation] until birth) versus standard care (no medication administered).

Follow up was performed on women and their infants up to four months of age; longer term follow up may be possible subject to further successful funding.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Intrauterine foetal death
2. Adverse pregnancy complications (including pre-eclampsia, preterm birth, infant small for gestational age, neonatal death)

These will be assessed during the antenatal period (in relation to side effects of medication) and after the time of birth for birth and postpartum outcomes.

Secondary outcome measures
1. Adverse neonatal outcomes
2. Adverse maternal outcomes
3. Maternal quality of life and emotional wellbeing: this will be assessed at four months postpartum using standard questionnaires (the Edinburgh depression scale; the 36-item Short Form health survey [SF-36] and the Speilberger anxiety trait questionnaires)
4. Placental pathology

These will be assessed during the antenatal period (in relation to side effects of medication) and after the time of birth for birth and postpartum outcomes.

Overall study start date
21/03/2007

Completion date
28/02/2010

Eligibility

Key inclusion criteria
1. Women with a singleton pregnancy at 18 to 22 weeks gestation
2. Evidence of placental dysfunction in their current pregnancy as determined by two or more of the following:
a. abnormal ultrasonographic placental morphology
b. abnormal uterine artery Doppler waveforms
c. one or more abnormal biochemical markers on first or second trimester maternal serum screening

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
102 women

Key exclusion criteria
1. Women with known positive thrombophilic screening
2. Known lethal foetal anomaly
3. Any contraindication to heparin therapy or continuation of the pregnancy (e.g., chorioamnionitis requiring delivery)
4. Clinical need for heparin therapy during pregnancy (e.g., previous venous thrombo-embolic episode)
5. Multiple pregnancy
6. Hypertension
7. Language barrier requiring official translator

Date of first enrolment
21/03/2007

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
Canada

Study participating centre
Department of Obstetrics & Gynecology
Toronto
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M5G 1Z4

Sponsor information

Organisation
University of Toronto (Canada)

Sponsor details
Mt Sinai Hospital
600 University Avenue
Toronto
Canada
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Sponsor type
University/education

Website
http://www.utoronto.ca/

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Research organisation

Funder Name
The Physicians Services Incorporated Foundation (Canada)

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