

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

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| Submission date 20/03/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 02/05/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 28/09/2009 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

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

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 Spielberger 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

Canada

M5G 1Z4

Sponsor information**Organisation**

University of Toronto (Canada)

Sponsor details

Mt Sinai Hospital

600 University Avenue

Toronto

Canada

M5G 1Z4

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