

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

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<b>Registration date</b> 02/05/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/09/2009	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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.

### **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**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

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## Sponsor information

**Organisation**

University of Toronto (Canada)

**ROR**

<https://ror.org/03dbr7087>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

The Physicians Services Incorporated Foundation (Canada)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

