Low molecular weight heparin (FRagmin (R)) in pregnant women with a history of Uteroplacental Insufficiency and Thrombophilia, a randomized trial (FRUIT-study).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20780

Source
NTR

Brief title
FRUIT-study

Health condition

The pregnant women are randomised after ultrasound confirmation of a viable intrauterine pregnancy to recieve daily dalteparin plus aspirin (starting before 12 weeks gestation) or aspirin only.

Sponsors and support

Primary sponsor: A single grant in the period 2000-2001 of Pharmacia and Upjohn.
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Reduction of preeclampsia before 34 weeks gestational age.

Secondary outcome

1. Reduction in spontaneous abortion, maternal admission to hospital and neonatal intensive care admission;

2. Increase in gestational age and weight at birth.

Study description

Background summary

Uteroplacental insufficiency resulting in preeclampsia, eclampsia, HELLP syndrome (hemolysis, elevated liver enzymes and low platelets) fetal growth restriction and preterm birth is one of the major problems in perinatal medicine.
The origin is multifactorioal and endothelial cell dysfunction is the final common pathway in the maternal syndrome preeclampsia. A substantial percentage of the women have thrombophilic disorders.
This multicenter open two-armed RCT will elucidate whether treatment with low molecular weight heparine during a following pregnancy is benificial for the maternal, fetal and neonatal morbidity and mortality.

Study objective

Low molecular weight heparin plus aspirin reduces the recurrence of preeclampsia and/or small for gestational age infants before 34 weeks gestational age in women with documented thrombophilia with a history of preeclampsia and/or small for gestational age infants with birth before 34 weeks.

Intervention

Two armed study:

A: Daily dalteparin (starting between 6-12 weeks pregnancy) throughout gestation plus aspirin (starting before 12 weeks gestation to 36 weeks);

B: Aspirin only (starting before 12 weeks to 36 weeks).

Both arms receive regular controls for women with a history of preeclampsia. In arm A: examination of Anti FActor Xa activity at 20 and 30 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with a history of preeclampsia and/or small for gestaitonal age infants before 34 weeks gestation and documented thrombophilia restricted to proteine c and proteine S deficiency, APC resistance, Factor V Leiden mutation, FActor II mutation, anticardiolipin antibodies, lupus anticoagulant;

2. Age > 18 years;

3. Informed consent.

Exclusion criteria

1. Antithrombine deficiency;

2. Diabetes mullitus;

3. Known malignancy;

4. Gastro-duodenic ulcer;

5. Severe renal or hepatic insufficiency;

6. Thrombo-embolism in history;

7. Hemorrhagic diathesis;

8. Idiopathic thrombocytopenia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-01-2000
Enrollment:	154
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL299
NTR-old	NTR337
Other	: N/A
ISRCTN	ISRCTN87325378

Study results

Summary results
This is the first trial with low molecular weight heparin in a population of women with a history of preeclampsia and will be submitted to an international journal.