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

Gepubliceerd: 11-09-2005 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20780

Bron
NTR

Verkorte titel
FRUIT-study

Aandoening

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.

Ondersteuning

Primaire sponsor: A single grant in the period 2000-2001 of Pharmacia and Upjohn.
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduction of preeclampsia before 34 weeks gestational age.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-01-2000
Aantal proefpersonen:	154
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.