# Low molecular weight heparin (FRagmin®) in pregnant women with a history of Uteroplacental Insufficiency and Thrombophilia: a randomised trial

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
20/12/2005		☐ Protocol	
Registration date 20/12/2005	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	[] Individual participant data	
30/11/2011	Pregnancy and Childbirth		

# Plain English summary of protocol

Not provided at time of registration

# Study website

http://www.nvog.nl

# Contact information

# Type(s)

Scientific

## Contact name

Prof J.I.P. de Vries

#### 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

## Acronym

FRUIT-study

## Study objectives

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.

# Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the local medical ethics committee

# Study design

Multicentre, randomised, active controlled, parallel group trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

## Participant information sheet

# Health condition(s) or problem(s) studied

Pre-eclampsia, Small for Gestational Age (SGA)

#### **Interventions**

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.

## **Intervention Type**

Drug

#### **Phase**

**Not Specified** 

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

Dalteparin, aspirin

## Primary outcome measure

Reduction of preeclampsia before 34 weeks gestational age.

# Secondary outcome measures

- 1. Reduction in spontaneous abortion, maternal admission to hospital and neonatal intensive care admission
- 2. Increase in gestational age and weight at birth

## Overall study start date

20/01/2000

## Completion date

31/12/2009

# **Eligibility**

## Key inclusion criteria

- 1. Patients with a history of preeclampsia and/or small for gestational age infants before 34 weeks gestation and documented thrombophilia restricted to protein C and protein S deficiency, Activated Protein C (APC) resistance, Factor V Leiden mutation, Factor II mutation, anticardiolipin antibodies, lupus anticoagulant
- 2. Aged greater than 18 years
- 3. Informed consent

## Participant type(s)

Patient

## Age group

Adult

# Lower age limit

18 Years

#### Sex

Both

# Target number of participants

## Key exclusion criteria

- 1. Antithrombin deficiency
- 2. Diabetes mellitus
- 3. Known malignancy
- 4. Gastro-duodenic ulcer
- 5. Severe renal or hepatic insufficiency
- 6. Thrombo-embolism in history
- 7. Hemorrhagic diathesis
- 8. Idiopathic thrombocytopenia

### Date of first enrolment

20/01/2000

## Date of final enrolment

31/12/2009

# Locations

## Countries of recruitment

Netherlands

# Study participating centre

**VU Medical Center** 

Amsterdam Netherlands 1007 MB

# Sponsor information

# Organisation

VU University Medical Center (The Netherlands)

## Sponsor details

Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT

## Sponsor type

University/education

#### Website

http://www.vumc.nl/zorg/

## ROR

https://ror.org/00q6h8f30

# Funder(s)

# Funder type

Industry

## Funder Name

Pharmacia & Upjohn Company (The Netherlands)

# **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

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No