

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

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

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

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

Study type(s)

Treatment

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(s)

Reduction of preeclampsia before 34 weeks gestational age.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Industry

Funder Name

Pharmacia & Upjohn Company (The Netherlands)

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes