ISRCTN87325378 https://doi.org/10.1186/ISRCTN87325378

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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
30/11/2011

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
VU Medical Center
Department of Obstetrics and Gynaecology
P.O. Box 7057
Amsterdam
Netherlands
1007 MB
JIP.deVries@VUMC.nl

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