ISRCTN53717039 https://doi.org/10.1186/ISRCTN53717039

Effectiveness of dalteparin therapy as intervention in recurrent pregnancy loss

Submission date	Recruitment status	[_] Prospectively registered
13/11/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/04/2020	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Ekkehard Schleussner

Contact details
Department of Obstetrics
Friedrich Schiller University
Bachstr. 18
Jena
Germany
D-07740
-
ekkehard.schleussner@med.uni-jena.de

Additional identifiers

Clinical Trials Information System (CTIS)
2006-001984-53

Protocol serial number
EudraCT-No.: 2006-001984-53

Study information

Scientific Title
Effectiveness of dalteparin therapy as intervention in recurrent pregnancy loss

Acronym
ETHIGII

Study objectives
This study aims at analysing if the rate of pregnancy losses before the 24th week of gestation can be reduced by dalteparin (low molecular heparin) treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission of the Friedrich Schiller University Jena, Faculty of Medicine (Ethikkommission der Friedrich-Schiller-Universität Jena, Medizinischen Fakultät), approval received on October, 26th, 2006 (reference number: 1837-08/06).

Study design
Open-label, randomised, two-armed, parallel-group, multi-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnant women with a history of recurrent pregnancy loss

Interventions
Patients will be randomised between:
1. Dalteparin 5000 IE daily and multivitamin two tablets daily
2. Multivitamin two tablets daily
Treatment duration: up to the 24th week of gestation

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dalteparin and multivitamin

Primary outcome(s)
Ongoing intact pregnancy at 24 weeks of gestation

Key secondary outcome(s))

1. Live birth
2. Late pregnancy complication, defined as at least one of the following:
a. preterm delivery (before 37 weeks of gestation)
b. placenta insufficiency
c. intrauterine growth restriction less than fifth percentile
d. preeclampsia
e. abruptio placentae
3. Foetus with structural anomalies
4. Symptomatic thromboembolic events
5. Side effects of dalteparin therapy (e.g. thrombocytopenia, osteoporosis, haemorrhage)

Completion date
13/01/2011

Eligibility

Key inclusion criteria
1. Single pregnancy, fifth to eighth week of gestation
2. Documented foetal heart activity in UltraSound (US)
3. History of recurrent pregnancy loss, defined as:
a. two or more early (less than 12 weeks of gestation) pregnancy losses, or
b. one or more late (more than 12 weeks of gestation) pregnancy loss
4. Aged more than 18 years
5. Written informed consent of the patient

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
449

Key exclusion criteria
1. Previous pregnancy losses caused by foetal structural or chromosomal anomalies
2. Uterine anomalies
3. Maternal infection, which caused previous pregnancy loss
4. Risk group II or III according to EThIG study (Effectiveness of Thromboseprophylaxe as intervention in the Gravidität) risk stratification (clinical need for heparin prophylaxis)

5. Acute thromboembolic event (need of heparin therapy)
6. Known hypersensitivity to any of the trial drugs or its ingredients (i.e. thrombocytopenia type II caused by allergic reaction to heparin
7. Anti-phospholipid antibody syndrome
8. Diabetes mellitus
9. Ongoing nicotine or drug or alcohol abuse
10. Human Immunodeficiency Virus (HIV) positive
11. Expected low compliance (e.g. by travel distance to trial site)
12. Current or recent (within 30 days prior to start of trial treatment) treatment with another investigational drug or participation in another investigational trial

Date of first enrolment
13/11/2006

Date of final enrolment
13/01/2011

Locations

Countries of recruitment
Germany

Study participating centre
Department of Obstetrics
Jena
Germany
D-07740

Sponsor information

Organisation
Friedrich Schiller University Jena (Friedrich-Schiller-Universität Jena) (Germany)

ROR
https://ror.org/05qpz1x62

Funder(s)

Funder type
Industry

Funder Name

The study will be funded by Pfizer Pharma GmbH, Karlsruhe (Germany)

Funder Name
The baseline medication (Femibion 800 Folsäure Plus Metafolin) will be supplied by Merck Pharma GmbH, Darmstadt (Germany)

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?
Basic results			21/04/2020	No	No