

# Effectiveness of dalteparin therapy as intervention in recurrent pregnancy loss

<b>Submission date</b> 13/11/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/04/2020	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

**Protocol serial number**  
EudraCT-No.:

## 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?
<a href="#">Basic results</a>			21/04/2020	No	No