ISRCTN78732833 https://doi.org/10.1186/ISRCTN78732833

Impact of dalteparin in pregnancy

Submission date
18/04/2008

Recruitment status
No longer recruiting

Registration date
29/04/2008

Overall study status
Completed

Last Edited
30/12/2020

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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CER Sainte-Justine 1006

Study information

Scientific Title

Dalteparin in prevention of recurrence of severe obstetrical complications in women without thrombophilia

Study objectives
A prophylactic dose of dalteparin may prevent the recurrence of placental mediated complications in women without thrombophilia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Comité déthique de recherche (CER) du CHU Sainte-Justine on the 16th March 2000 (ref: 1006).

Study design
Randomised open 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
Severe obstetrical complications

Interventions
Randomisation (1:1) to dalteparin (5000 IU daily) versus no treatment from randomisation until 36 - 37 weeks of pregnancy. Total duration of follow-up for all treatment arms will be from randomisation until departure from the hospital after delivery.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure

Composite outcome of one of:
1. Severe preeclampsia
2. Severe IUGR
3. Major abruptio placentae

Primary outcomes will be measured at delivery.

Secondary outcome measures
1. Non-severe preeclampsia, measured at delivery
2. Non-severe IUGR, measured at delivery
3. Gestational age at delivery, measured at delivery
4. Pregnancy complications, measured at delivery
5. Hospitalisation length, measured at delivery and departure from the hospital after delivery
6. Admission to intensive care unit, measured at departure from the hospital after delivery

Overall study start date
16/03/2000

Completion date
20/06/2007

Eligibility

Key inclusion criteria
1. Normal thrombotic screen
2. Female patients aged more than 17 years
3. Pregnancy less than 17 weeks
4. Signature of the consent form
5. One of the following in previous pregnancy:
5.1. Severe preeclampsia with delivery less than 34 weeks
5.2. Severe intrauterine growth restriction (IUGR)
5.3. Abruptio placentae with delivery less than 34 weeks or foetal death
5.4. One idiopathic foetal death after 20 weeks
5.5. Two or more of idiopathic foetal death between 12 - 19 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
276

Total final enrolment
116

Key exclusion criteria
1. Multiple pregnancy
2. Alcohol or illicit drug use
3. Severe medical condition other than chronic hypertension
4. Foetal malformation or chromosomal anomaly
5. Uterine malformation or infection
6. Abdominal trauma
7. Any known cause of foetal death

Date of first enrolment
16/03/2000

Date of final enrolment
20/06/2007

Locations

Countries of recruitment
Canada

Study participating centre
3175 Côte sainte-Catherine
Montreal (QC)
Canada
H3T 1C5

Sponsor information

Organisation
Canadian Foundation for Women's Health (Canada)

Sponsor details
780 Echo Drive
Ottawa (ON)
Canada
K1S 5R7
+1 800 561 2416
helpdesk@sogc.com

Sponsor type
Research organisation

Website
http://www.cfwh.org

ROR
https://ror.org/0278syk25

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Foundation for Women's Health (Canada)

Funder Name
Pharmacia and Upjohn Inc. (USA)

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	01/01/2009	30/12/2020	Yes	No