Highlow study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23452

Source
NTR

Health condition

To evaluate the efficacy and safety of intermediate dose LMWH versus fixed low dose LMWH in pregnant women with a history of previous deep venous thrombosis or pulmonary embolism.

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: GlaxoSmithKline, NWO, Academic Medical Center

Intervention

Outcome measures

Primary outcome

1. Symptomatic DVT during pregnancy and 6 weeks postpartum;

2. Symptomatic PE during pregnancy and 6 weeks postpartum.

Secondary outcome

1. Symptomatic DVT during pregnancy until 3 months postpartum;

2. Symptomatic PE during pregnancy until 3 months postpartum.

Study description

Background summary

This is a randomized-controlled open-label trial comparing two different doses of LMWH in pregnant patients with a history of previous VTE. Both doses are recommended doses in the ACCP guidelines.

Patients enter the study as soon as a home test confirms pregnancy. LWMH will be administered until 6 weeks postpartum. Follow-up will continue until 3 months postpartum.

Patients will be recruited by their treating physician, either an obstetrician or internist.

Study objective

Intermediate weight-adjusted dose LMWH for VTE prophylaxis in pregnant women with a previous history of VTE is more efficacious than fixed low dose LMWH without increasing bleeding risk.

Study design

1. Inclusion (visit);

2. 2 weeks after treatment (visit);

3. 20 weeks after treatment (phone or visit);

4. 30 weeks after treatment (phone or visit);

5. 1 week after delivery (phone or visit);

6. 6 weeks after delivery (phone);

7. 3 months after delivery (phone).

Intervention

Intermediate dose LMWH. Two different doses will be tested. LWMH will be administered until 6 weeks postpartum.

Low doses: Nadroparin (Fraxiparine): 2850 IE 1dd1 s.c.; dalteparin (Fragmin): 5000 IU 1dd1 s.c.; tinzaparin (Innohep): 4500 IU 1dd1 s.c.; enoxaparin (Clexane): 40 mg 1dd1 s.c.

Intermediate doses: weight adjusted according to dosing scheme in protocol.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. Pregnancy confirmed by urinary pregnancy test;

3. Gestational age < 14 weeks since first day of last menstrual period;

4. Previous objectively confirmed VTE, either unprovoked, in the presence of use of oral contraceptives or estrogen/progestagen use, or related to pregnancy or the postpartum period, or minor risk factors (e.g. long distance travel, minor trauma).

Exclusion criteria

1. Previous VTE related to a major provoking risk factor (e.g. surgery, major trauma or plaster cast immobilisation in the 3 months prior to VTE) as the sole risk factor;

2. Indication for treatment with therapeutic dose anticoagulant therapy (e.g. treatment of acute VTE; permanent use of therapeutic anticoagulants outside of pregnancy);

3. Inability to provide informed consent;

4. Type 1 allergy to LMWH preparations;

5. Confirmed heparin-induced thrombocytopenia;

6. Renal insufficiency (creatinine clearance < 30ml/min);

7. Previous inclusion in the Highlow study (for another pregnancy).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2013
Enrollment:	1000
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-03-2013

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55412
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3731
NTR-old	NTR3894
CCMO	NL40326.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON55412

Study results

Summary results
N/A