Highlow study.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23452

Bron
Nationaal Trial Register

Aandoening

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.

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: GlaxoSmithKline, NWO, Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Symptomatic DVT during pregnancy and 6 weeks postpartum;
2. Symptomatic PE during pregnancy and 6 weeks postpartum.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-03-2013
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55412
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A