Anticoagulants for living fetuses for women with recurrent miscarriage and inherited blood clotting disorders.

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Low molecular weight heparin increases live birth in women with recurrent miscarriage and inherited thrombophilia when compared to no treatment.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27965

Bron
NTR

Verkorte titel
ALIFE2 study

Aandoening

recurrent miscarriage
inherited thrombophilia

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is life birth. Women in both study arms will be followed-up until delivery or until another (adverse) pregnancy outcome has occurred (e.g. miscarriage, termination of pregnancy, etc.).

Toelichting onderzoek

Achtergrond van het onderzoek

In the ALIFE2 study women with recurrent miscarriage and inherited thrombophilia will be randomised to either low molecular weight heparin or standard pregnancy surveillance in a subsequent pregnancy. The study is designed to evaluate the effect of low molecular weight heparin on live birth in these women.

Doel van het onderzoek

Low molecular weight heparin increases live birth in women with recurrent miscarriage and inherited thrombophilia when compared to no treatment.

Onderzoeksopzet

1. Outcome 1: Gestational age of 12 weeks;

2. Outcome 2: Gestational age of 24 weeks;

3. Outcome 3: Delivery and/or end of pregnancy.

Onderzoeksproduct en/of interventie

Women in the intervention arm of the study will receive intermediate dose low molecular weight heparin once daily, started immediately after randomisation until delivery. Apart from this intervention they will receive standard pregnancy surveillance.

Women in the second arm of the study will receive no intervention on top of standard pregnancy surveillance.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women with recurrent miscarriage (>= 2) irrespective of gestational age;

2. Confirmed inherited thrombophilia; factor V Leiden mutation, prothrombin gene mutation (G20210A), protein S deficiency, protein C deficiency or antithrombin deficiency or a combination hereof. Protein S, -C and antithrombin deficiencies need to be confirmed by two independent tests, performed on two separate occasions and not during pregnancy or anticoagulant therapy;

3. Pregnancy confirmed by urine pregnancy test;

4. Age 18 - 42 years at randomisation;

5. Willing and able to give informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Duration of current pregnancy >= 7 weeks;

2. Indication for anticoagulant treatment during pregnancy (for instance prosthetic heart valves, a history of venous thromboembolism or antiphospholipid syndrome);

3. Contraindications to LMWH (previous heparin induced thrombocytopenia, active bleeds or renal insufficiency with creatinine clearance of less than 30ml/min);

4. Known allergy to at least 3 different LMWH preparations;

5. Previous inclusion in the ALIFE2 study (for another pregnancy).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	399
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3210
NTR-old	NTR3361
Ander register	EudraCT : 2012-001447-43
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A