Aspirine and/or low-molecular weight heparin for women with unexplained recurrent miscarriages and/or intra-uterine fetal death.

Gepubliceerd: 09-06-2005 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON26868

Bron
NTR

Verkorte titel
ALIFE - Anticoagulants for Living Fetuses

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Live birth rate.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

There is reasonable evidence to suggest that some cases of recurrent pregnancy loss (RPL), including recurrent miscarriage (RM) and/or later intra-uterine fetal death, are associated with placental thrombosis and infarction. Approximately 5% of women experience two or more consecutive pregnancy losses. Recurrent miscarriage, defined as two or more spontaneous first trimester pregnancy losses, may affect as many as 1% to 2% of women of reproductive age. The prognosis in subsequent pregnancies of women with RM or late fetal death is a rate of live birth of approximately 65% and 50%, respectively, without any therapeutic intervention. Some hematologic conditions, as the antiphospholipid syndrome (APLS) are associated with RPL. Compared to controls, women with familial thrombophilia, especially those with combined defects or antithrombin deficiency, have an increased risk of RM (odds ratio: 1.35) and late fetal death (odds ratio: 3.6). Heparin and low-dose aspirin have been shown to be effective and safe in reducing the pregnancy loss rate in patients with APLS, with significantly better pregnancy outcome than low dose aspirin alone. While several non-randomized studies have suggested that anticoagulant therapy in women with RPL with or without thrombophilia may be of benefit resulting in an increased live birth rate, strong evidence based on randomized-controlled trial is still lacking. The aim of the present trial is to evaluate the efficacy of different anticoagulant therapies in women with RPL with or without thrombophilia.

Study design:

Randomized, prospective, multicenter, open-label study, double blinded for aspirin administration.

Study protocol:

After inclusion in the study, patients will be randomized to the following groups:
1) Placebo;

2) carbasalate calcium 100 mg/day

3) carbasalate calcium 100 mg/day plus low dose LMWH s.c..

Placebo or low-dose aspirin is given from inclusion until 36 weeks of gestation. LMWH is given from 7 weeks gestation confirmed by fetal heartbeat throughout gestation.

Sample size: 91 women per arm, total sample size 273.

Doel van het onderzoek

N/A

Onderzoeksproduct en/of interventie

1. Placebo;

2. Aspirin (carbasalate calcium);

3. Aspirin (carbasalate calcium);

4. Combined with low-molecular-weight heparin.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Women with at least 2 unexplained miscarriages and/or intra-uterine fetal deaths.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous thromboembolism;

2. Antiphospholipid Syndrome (APLS);

3. Uterine abnormalities;

4. Patients' or their partners' abnormal karyotype;

5. Indication for anticoagulant treatment during pregnancy (for instance prostetic heart valves);

6. Metabolic and toxic factors (diabetes mellitus, radiation exposure);

7. Known erytrocyte antibody anti-P syndrome;

8. Pregnancy losses due to documented fetal malformation or the result of an infectious complication;

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

10. Previous inclusion in the ALIFE trial (for another pregnancy).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2004
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-06-2005
Soort:	Eerste indiening

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	NL170
NTR-old	NTR206
Ander register	: N/A
ISRCTN	ISRCTN58496168

Resultaten

Samenvatting resultaten

N/A