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

No registrations found.

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

Summary

ID

NL-OMON26868

Source
NTR

Brief title
ALIFE - Anticoagulants for Living Fetuses

Intervention

Outcome measures

Primary outcome

Live birth rate.

Secondary outcome

1. Prevalence of adverse pregnancy outcomes:

a. Preeclampsia;

b. HELLP;

c. Intrauterine growth retardation;

d. Premature delivery;

e. Congenital malformations
prevalence of thromboembolic and hemorragic complications;

f. Thrombocytopenia;

g. Allergic reactions.

Study description

Background summary

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.

Study objective

N/A

Intervention

1. Placebo;

2. Aspirin (carbasalate calcium);

3. Aspirin (carbasalate calcium);

4. Combined with low-molecular-weight heparin.

Contacts

Public
Academic Medical Center (AMC), Department of Vascular Medicine, F4-276,
P.O. Box 22660
S. Middeldorp
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5665976
Scientific
Academic Medical Center (AMC), Department of Vascular Medicine, F4-276,
P.O. Box 22660

S. Middeldorp
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5665976

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2004
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-06-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL170
NTR-old	NTR206

Register	ID
Other	: N/A
ISRCTN	ISRCTN58496168

Study results

Summary results
N/A