Modulation of the cardiovascular and immunologic characteristics by aerobic exercise in women with recurrent miscarriage

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To study the effects of physical training on vascular, endothelial and immunologic functioning in women with recurrent miscarriage; results are compared with women who have never been pregnant (nulligravid controls) and women who have a history of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Abortions and stillbirth
Study type	Observational invasive

Summary

ID

NL-OMON33581

Source
ToetsingOnline

Brief title
Improvement of haemodynamics in women with recurrent miscarriage

Condition

- Abortions and stillbirth
- Vascular hypertensive disorders

Synonym
recurrent miscarriage, spontaneous abortions

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: exercise, haemodynamic, immune system, recurrent miscarriage

Outcome measures

Primary outcome

Primary outcome of the study: plasmavolume expansion

Secondary outcome

Secondary study parameters:

Increase exercisetollerance (VO2 max)

Increase venous and arterial compliance

decrease vascular resistance in uterine artery

Increase endothelial functioning

Improvement immunologic profile (decrease T-cell activation, decrease NK

cytotoxic activity)

Increase glucose and lipid profile

Improvement cardiac output

Study description

Background summary

Recurrent miscarriage is defined as 2 or more spontaneous miscarriages, with a gestational age under 16 weeks. The incidence of recurrent miscarriages in the Netherlands is around 3% in women of fertile age. In very early gestation embryonal factors are more often involved, while spontaneous miscarriage after 6 weeks gestation more often involve maternal factors.

The exact etiology of recurrent miscarriage can only me found in less than 50% percent of the patients. Uptill now known maternal factors are: thrombophilia, auto-immune disease, uterus anomalies and hyperhomocysteinaemia. Furthermore women with recurrent miscarriage have an increased resistance in the uterine artery. The latter observation suggests abnormal haemodynamic functioning; which is likely to be associated with the increased risk of preeclampsia in women with recurrent miscarriage in a next (ongoing) pregnancy. Also, both women with a history of preeclampsia as women with a history of recurrent miscarriage haven an increased life-time risk of cardiovascular disease. Furthermore, women with recurrent miscarriages often have immunologic abnormalities, characterized by increased T-cel activation and disbalance between regulatory and cytotoxic "natural killer cells". This immunologic disbalance is likely one of the negative factors involved in reproductive failure.
It is known that exercise has a possitive effect on pregnancy and the riskprofile associated with cardiovascular disease and the immune systeme. Possibly also women with recurrent miscarriage can improve their haemodynamic functioning by physical exercise; it would be an advantage if this would improve the cardiovascular adjustment and a more beneficial immune response to the early pregnancy. Plasma volume expansion is an important factor in this adjustment. Therefore, in this pilot study, we would like to study the effects of one month training on the haemodynamic functioning and the immune profile in women with recurrent miscarriage.

Study objective

To study the effects of physical training on vascular, endothelial and immunologic functioning in women with recurrent miscarriage; results are compared with women who have never been pregnant (nulligravid controls) and women who have a history of an uncomplicated pregnancy (primiparous controls)

Study design

Prospective intervention study

Study burden and risks

The burden associated with participation is mainly the time intensive aspect of the study. Participants have a 4 weeks training programm with cardiovascular evaluation befor and after training. The training itself is not associated with any known risks.

Participants will be asked to have a constant sodium intake in the advance week of measurement, the total sodium intake is equal to the mean sodium intake. Based on experience with this sodium constant diet, we know that the diet is hardly considered to be any burden.

To determine plasma volue, labeled albumine delution method is used. The nuclear medicine departmet is well known with this procedure. The radiation exposure is minimal and is similar to the radiation exposure during a one-way flight to Amsterdam- New York. The radiation exposure according "the international commision on radiological protection (ICRP)" is categorie 1 ("Trivial level of risk and minor level of social benefit required*).

During the study mostly non-invasive measurements of minimal burden are used to measure cardiovascular functioning. Invasive procedure is minmised to the use of two intravenous canulas. These canulas are used for bloodsampling and determination of plasma volume after HSA I-125. During the study no medication is used that is aimed to have health effects. Insufflation of the cuffs around arm and leg is unpleasant. We are aware of the fact that there are women who will experience discomfort with the transvaginal ultrasound measurement of the doppler flow in the uterine artery. Because of the nature of this examination, this measurement will take place at the department most familiar and specialized with this technique.

In summary the burden and risk of participants is mainly considered to be time extensive. Invasive aspect is minimal. On the other hand; there is likely to be a positive health effect of physical exercise on physical and mental wellbeing.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients: women with at least two clinically objectified spontaneous abortions

Exclusion criteria

- auto immune disease
- diabetes
- smoking
- pregnancy
- use of medication known to interfere with cardiovascular system (anti coagulant drugs, antihypertensive drugs, statins, etc...)
- incapability to perform physical exercise

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2009
Enrollment:	30

Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	09-04-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL24854.091.08