Natural Killer cell phenotype in unexplained recurrent miscarriages

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26396

Source
Nationaal Trial Register

Brief title
OVIDE

Health condition

Unexplained recurrent miscarriages

Sponsors and support

Primary sponsor: Academic Hospital Maastricht, Department of Obsterics and Gynaecology
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Percentage of NK cells with an activating phenotype in peripheral blood

Secondary outcome

- Percentage of NK cells with an activating phenotype in menstrual blood

- VO2 max: measured in millilitres per kilogramme of body weight per minute
- Lifestyle questionnaire: Simple Lifestyle Indicator Questionnaire (SLIQ) score
- Total body water: fat free mass in kilogramme of body weight

Study description

Background summary

The uterus allows implantation of the embryo during pregnancy. In particular, the immunological environment of the uterus is of great importance, since it must be able to tolerate foreign paternal antigens. Earlier research has shown that the immune cell population in the uterus is unique and that particularly natural killer (NK) cells play a special role in creating a tolerant immunological environment of the uterus for pregnancy. Despite exciting advances in understanding the role of natural killer cells during pregnancy, considerably more work needs to be done to establish a specific role for natural killer cells in unexplained recurrent miscarriages (URM). Therefore, in this innovative study we will try to provide further insight in the role of NK cells in URM by studying 20 unique NK cell markers. These will be studied both systemically in peripheral blood and locally in menstrual blood. Furthermore, this study will provide more information on the influence of physical health. In this way, we hope to expand understanding of the specific role of NK cells in URM.

Study objective

We hypothesize a higher percentage of NK cells with an activating phenotype in women with URM hereby causing rejection of implantation of the embryo. We expect a similar trend in menstrual blood. We expect that an activating NK cell phenotype is related to poor physical health (unhealthy lifestyle factors and low VO2max).

Study design

Women who are willing to participate in the study will first be asked to fill out a lifestyle questionnaire, next peripheral blood will be sampled with a venapunction and last VO2max will be
measured during cycling. On the same day, participants will be asked to sample their urine and menstrual blood during their next menstrual cycle and return it to the hospital. The duration of the study for one participant is, depending on the moment of their menstrual cycle, maximal + 5 weeks from the visit when measurements take place.

Intervention

None

Contacts

Public
Maastricht UMC+
Denise Habets

0031433874152
Scientific
Maastricht UMC+
Denise Habets

0031433874152

Eligibility criteria

Inclusion criteria

Group 1:
Recurrent (>2) unexplained miscarriages, defined by normal parental karyotype, no maternal thrombophilia and no uterine abnormality
Group 2:
Previous uncomplicated pregnancy, defined by healthy live birth after 37 weeks of gestation without major obstetric complications

Exclusion criteria

- Current or recent (<3 months ago) pregnancy
- Current or recent (<2 weeks) symptomatic genital infection such as chlamydia, gonorrea or pelvic inflammatory disease.
- Younger than 18 or older than 36 years
- Unable to give consent in Dutch

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2019
Enrollment:	126
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-01-2020
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	NL8287

Register	ID
Other	METC azM/UM : METC18-026

Study results