Natural Killer cell phenotype in unexplained recurrent miscarriages

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26396

Bron
Nationaal Trial Register

Verkorte titel
OVIDE

Aandoening

Unexplained recurrent miscarriages

Ondersteuning

Primaire sponsor: Academic Hospital Maastricht, Department of Obsterics and Gynaecology
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of NK cells with an activating phenotype in peripheral blood

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Maastricht UMC+
Denise Habets

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Wetenschappelijk

Maastricht UMC+
Denise Habets

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2019
Aantal proefpersonen:	126
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-01-2020
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	NL8287
Ander register	METC azM/UM : METC18-026

Resultaten