

# Natural killer cell receptor variability during the menstrual cycle

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The purpose of this pilot study is to describe the changes in NK cell percentages and therefore is hypothesis generating rather than hypothesis testing

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

## Samenvatting

### ID

NL-OMON29470

### Bron

NTR

### Verkorte titel

LILAC

### Aandoening

Not applicable

### Ondersteuning

**Primaire sponsor:** Academic Hospital Maastricht, Department of Obstetrics and Gynaecology

**Overige ondersteuning:** None

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Percentage of NK cells with activating and inhibitory receptors in peripheral blood

# Toelichting onderzoek

## Achtergrond van het onderzoek

The human menstrual cycle is a complex physiological process with profound effects on many organs and systems in the body including the immune system. Part of the innate immune system, peripheral blood NK cells show dynamic changes in number as well as cytotoxicity during the menstrual cycle, but the exact nature and consequence of these changes is not yet understood. In the present study, we characterize the variation in the natural killer cell receptors associated with different phases of the menstrual cycle in women with a natural menstrual cycle and also in men. We compare activating and inhibitory peripheral natural killer cell receptors at strictly defined follicular (day 7) and luteal (day 21) phases of the menstrual cycle. The results will advance our understanding of the timing and consequence of the natural hormonal cycle on immune environment.

## Doel van het onderzoek

The purpose of this pilot study is to describe the changes in NK cell percentages and therefore is hypothesis generating rather than hypothesis testing

## Onderzoeksopzet

Women and men will be asked to visit the TVDC to sample peripheral blood with a venapunction at day 1, 7 and 21 of the menstrual cycle during 2 consecutive cycles. Furthermore, women will be asked to sample menstrual blood at day 1 of the menstrual cycle during 2 consecutive cycles.

## Onderzoeksproduct en/of interventie

None

# Contactpersonen

## Publiek

Maastricht UMC+  
Denise Habets

0031433874152

## **Wetenschappelijk**

Maastricht UMC+  
Denise Habets

0031433874152

## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

Group 1: healthy women (no chronic medical conditions like chronic hypertension, chronic kidney failure, chronic immune conditions (SLE) or chronic medication use) with a regular natural menstrual cycle of 28 days (+/- 3 days), defined by no contraceptive use or healthy women with a copper spiral

Group 2: healthy men (no chronic medical conditions, like chronic hypertension, chronic kidney failure, chronic immune conditions (SLE) or chronic medication use)

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

- Current or recent (<2 weeks) symptomatic infection
- Previous pregnancy with complications, such as repeated miscarriages, preeclampsia, or diabetes gravidarum
- Unable to give mentally capable consent in Dutch

## **Onderzoeksopzet**

### **Opzet**

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

## Deelname

Nederland  
Status: Werving gestart  
(Verwachte) startdatum: 01-04-2020  
Aantal proefpersonen: 12  
Type: Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

### Toelichting

Not applicable

## Ethische beoordeling

Positief advies  
Datum: 03-06-2020  
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	NL8701
Ander register	METC azM/UM : METC19-054

# Resultaten

## Samenvatting resultaten

Not applicable