NATURAL KILLER CELL RECEPTOR VARIABILITY DURING THE MENSTRUAL CYCLE

Published: 15-04-2020 Last updated: 10-04-2024

The main goal of this study is to analyse the influence of the menstrual cycle on NK cell receptor variability.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immunodeficiency syndromes
Study type	Observational invasive

Summary

ID

NL-OMON50034

Source ToetsingOnline

Brief title LILAC

Condition

- Immunodeficiency syndromes
- Menstrual cycle and uterine bleeding disorders

Synonym Menstrual cycle

Research involving Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: Menstrual cycle, Natural Killer cell

Outcome measures

Primary outcome

Percentage of NK cells with activating and inhibitory receptors in peripheral

blood.

Secondary outcome

Percentage of NK cells with activating and inhibitory receptors in menstrual

blood.

Percentage of degranulation of NK cells in peripheral blood.

Percentage of degranulation of NK cells in menstrual blood.

Study description

Background summary

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 in 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.

Study objective

The main goal of this study is to analyse the influence of the menstrual cycle on NK cell receptor variability.

Study design

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.

Study burden and risks

The burden of the study is limited to six venapunctions at six different time points and sampling of menstrual blood. There are no risks associated with participation and there is no personal benefit for participation. By means of participation, more knowledge can contribute to gaining more insight in the influence of the menstrual cycle on the immune system.

Contacts

Public

Medisch Universitair Ziekenhuis Maastricht

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

3 - NATURAL KILLER CELL RECEPTOR VARIABILITY DURING THE MENSTRUAL CYCLE 13-05-2025

Elderly (65 years and older)

Inclusion criteria

Healthy women between the age of 18 and 36 with no chronic medical conditions, like chronic hypertension, chronic kidney failure, chronic immune conditions (SLE) or chronic medication use, with a natural menstrual cycle, defined by no contraceptive use and healthy women with a copper spiral Healthy men between the age of 18 and 36 with no chronic medical conditions, like chronic hypertension, chronic kidney failure, chronic immune conditions (SLE) or chronic medication use

Exclusion criteria

- 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

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:	Recruitment stopped
Start date (anticipated):	01-07-2020
Enrollment:	12
Туре:	Actual

Ethics review

Approved WMO	
Date:	15-04-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	01-07-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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 CCMO **ID** NL70964.068.19