

# The influence of fetal seks on the maternal immunity

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Immune disorders NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON43005

### Source

ToetsingOnline

### Brief title

Fetal seks and maternal immunity

### Condition

- Immune disorders NEC
- Maternal complications of pregnancy

### Synonym

preeclampsia, preterm birth

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** fetal sex, pregnancy, reproductive immunology

## Outcome measures

### Primary outcome

Primary outcomes of the study will be levels of T cells and macrophage cell subsets. These levels will be analysed and compared between both groups.

### Secondary outcome

Secondary outcomes will be the effects of maternal blood stimulation by fetal leukocytes.

## Study description

### Background summary

Adaptation of the maternal immune system to accommodate the semi-allogeneic fetus is necessary for pregnancy success. Dysregulation of this immune adaptation is implicated in reproductive disorders as infertility, recurrent miscarriage, fetal growth restriction, and preeclampsia. The mechanisms being responsible for fetal tolerance are not known. Several T cell subsets have been implicated in fetal tolerance. Interestingly, associations have been found between fetal sex and complicated pregnancy outcomes. Male fetuses are more often born preterm, and pregnancies with male fetuses are more often complicated by preeclampsia and gestational diabetes mellitus. The pathophysiological pathways responsible for these associations are not known. A possible pathway could be fetal sex dependent maternal immune activation. In this study we will analyse the effects of fetal sex on the maternal immune system.

### Study objective

The main objective of this study is to analyse the effect of fetal sex on levels of T and macrophage cell subsets in decidual tissue. Secondary objectives will be to analyse differences in the effect of maternal blood stimulation by fetal leukocytes of male and female fetuses.

## Study design

This study is an observational study in which levels of T cells and macrophages will be analysed. To be able to compare this effect in both primiparous and multiparous women, both primiparous and multiparous women will be included. Leukocytes will be derived from decidual biopsies, taken from the placenta after delivery, and will be analysed using multicolour flow cytometry and RT-PCR. Levels and subsets of macrophages and T cells and its deriving cytokines will be analysed. Furthermore, maternal peripheral blood will be stimulated by fetal cord blood.

## Study burden and risks

Biopsies will be taken from placental tissue after delivery. As maternal blood will be taken during routine blood sampling before the surgery and cord blood will be taken after fetal cord clamping this will not pose any risk on the individuals. This study investigates the pregnancy related immune changes in pregnancies; eventually these changes possibly are different in preeclampsia and therefore could potentially lead to therapies. Subjects have no direct benefits of this study.

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- healthy
- written informed consent
- 18-40 years
- scheduled for caesarean section (breech position, repeat section, elective)

### Exclusion criteria

- smoking
- immune related disorders
- fever / illness within the last month
- infertility treatment (ovulation induction, IVF-ICSI, intra uterine insemination)
- body mass index <18 or >30
- spontaneous start of labour

## 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):	15-08-2018
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	16-08-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL58331.042.16
Other	Under review <a href="https://clinicaltrials.gov">clinicaltrials.gov</a>