Different regulation of memory T cells in patients with preeclampsia

Published: 08-04-2016
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The main objective of this study is to analyse the effect of preeclampsia on levels of memory T cell subsets in peripheral blood.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON43397

Source
ToetsingOnline

Brief title
Preeclampsia and memory T cells

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
hypertensive disorder of pregnancy, preeclampsia

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: Immune, Memory T cells, Preeclampsia

Outcome measures

Primary outcome

Primary outcomes of the study will be levels of memory T cell subsets. These

levels will be analysed and compared between the different population groups.

Furthermore, these levels will be compared to levels of memory T cells found in

a previous study, analysing these levels in women with uncomplicated pregnancy

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Secondary outcome

Not applicable.

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, the incidence of immune related pregnancy disorders are higher in first pregnancies. However, women with a previous pregnancy complicated by preeclampsia have higher incidences of preeclampsia in subsequent pregnancies. These epidemiologic findings suggest a possible role for memory T cells. A previous study (manuscript in preparation) indeed showed short and long term effects of pregnancy on memory T cells. The effects of preeclampsia on memory T cells are not known. Possibly, pregnancies complicated by preeclampsia regulate memory T cells differently than uncomplicated pregnancy.

Study objective

The main objective of this study is to analyse the effect of preeclampsia on levels of memory T cell subsets in peripheral blood.

Study design

This study is an observational study in which levels of memory T cells will be analysed in 2 different groups. Peripheral blood, taken via an arm vein, will be analysed using multicolour flowcytometry. Levels and subsets of memory T cells will be analysed.

Study burden and risks

If possible blood samples will be taken by means of an extra blood sample taken at a routine sampling moment or blood will be taken at an extra blood sample moment at a suitable time point. This will not pose any risk on the individuals. This study investigates the pregnancy related immune changes in pregnancies complicated by preeclampsia, 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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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 ;Depending on the group subjects must either meet criteria 1 or 2
1. Pregnant in first pregnancy between 25-35 weeks (pregnant women) and complicated by preeclampsia
2. > 6 months after a pregnancy complicated by preeclampsia (former pregnant women)

Exclusion criteria

- smoking
- immune related disorders (other than preeclampsia)
- fever / illness within the last month
- infertility
- body mass index <18 or >30

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	08-04-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-03-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-10-2020
Application type:	Amendment
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	NL55954.042.15
Other	Under review bij clinicaltrials.gov