The role of pregnancy on susceptibility and antibody dependent enhancement of immune cells for Zika virus infection

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON50935

Source
ToetsingOnline

Brief title
Zika virus and pregnancy

Condition

- Viral infectious disorders
- Foetal complications

Synonym
Zika virus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Antibody dependent enhancement of infection, Pregnancy, Zika virus

Outcome measures

Primary outcome

The main endpoints of this study are the ZIKV titers measured in the

supernatant of infected PBMCs as well as the percentage of PBMCs that are

infected with ZIKV.

Secondary outcome

The secondary endpoints of this study are the cytokines detected in the

supernatant of infected PBMCs from pregnant women and non pregnant women.

Study description

Background summary

In 2015/2016 there was a major outbreak of the Zika virus in South America. This virus is transmitted by mosquitoes and is currently not found in the Netherlands. An infection with the Zika virus during pregnancy can lead to congenital birth defects. It is currently unclear how the Zika virus is transmitted from mother to child and what risk factors are for this transmission.

Study objective

The aim of this study is to determine whether white blood cells from pregnant women are more susceptible to infection with the Zika virus compared to white blood cells from non-pregnant women. We do this by collecting two tubes of blood from participants in this study and by examining whether the white blood cells isolated from the blood can become infected with the Zika virus.

Study design

Cross-sectional study

Study burden and risks

There is no benefit in participating this study, the burden and the risk of the intervention in this study (venapuncture) is negligible.

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

Pregnancy

Exclusion criteria

Pregnancy complications

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):	13-04-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	30-03-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL76727.078.21