

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

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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...

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Approved WMO               |
| <b>Status</b>                | Recruitment stopped        |
| <b>Health condition type</b> | Viral infectious disorders |
| <b>Study type</b>            | 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

### Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

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Rotterdam 3015GD  
NL

### 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

Pregnancy

### Exclusion criteria

## 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 |