# Serological diagnosis of Dengue virus infection in travellers; the impact of cross-reacting flaviviridae antigens.

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The main objective is to study the impact of cross-reactivity by other flaviviridae (Yellow Fever virus, Tick Born Encephalitis virus, West Nile virus, Japanese Encephalitis virus and Hepatitis C virus) on Dengue IgG serology using enzyme-linked...

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

## Summary

### ID

NL-OMON37829

**Source**
ToetsingOnline

**Brief title**
Cross-reacivity in Dengue IgG serology

### Condition

- Viral infectious disorders

**Synonym**
Breakbone fever

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** Dengue, flaviviridae, Serology

## Outcome measures

### Primary outcome

The main parameter is specificity and positive predictive value of the Dengue

IgG ELISA.

### Secondary outcome

nvt

# Study description

### Background summary

Dengue Fever is caused by the DENV virus which is transmitted by the Aedes Aegypti or Aedes Albopicto. As the habitat of this *tiger mosquito* is expanding, the risk of dengue becoming endemic is increasing in more temperate regions like the Netherlands. Primary infections are mostly asyptomatic, others experience flu-like symptoms and 2-3% of infections evolves to Dengue Hemorrhagic Fever(DHF) of Dengue Shock Syndrome(DSS). Severe diseases that are accompanied with extreme fever, hepatomegaly, plasma leakage and cardiovascular manifestations. In secondary infections the disease evolves into DHF or DSS more quickly. DENV infections are diagnosed using IgM and IgG serology, which is prone to false-positives due to other flaviviridae immunity. In order to improve dengue diagnostics a validation of current diagnostic tools and the identification of the precise impact of cross-reactivity is key.

### Study objective

The main objective is to study the impact of cross-reactivity by other flaviviridae (Yellow Fever virus, Tick Born Encephalitis virus, West Nile virus, Japanese Encephalitis virus and Hepatitis C virus) on Dengue IgG serology using enzyme-linked immune-assays(ELISA) and indirect immunofluorescense tests (IFT).

### Study design

Diagnostic validation case-control study as an internship project for a medical

student in the fourth year of medical school at the UMC St. Radboud Nijmegen.

**Study burden and risks**

A bloodsample will be obtained from the patient at one single occasion. A questionnaire concerning the vaccination history and travel history will be filled in.
The risks for the patient are the potential side-effects of venapunction, e.g. soreness and small haemorrhage at the puncture site.

# 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

The research population is defined as healthy volunteers (>18-years old) who received a Yellow Fever vaccination or a Tick Born Encephalitis vaccination.

### Exclusion criteria

Immuno-compromised patients or pregnancy.
Patients with known coagulopathias.

## Study design

### Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 02-07-2012 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 24-05-2012 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL40348.091.12 |