# Follow-up of the immune response ten years after intradermal or subcutaneous yellow fever vaccination

Published: 15-02-2017 Last updated: 14-04-2024

To investigate the long term (ten years) protective immune response to fractional yellow fever vaccination (1/5th of the standard dose, injected intradermally), compared to the standard subcutaneous vaccination

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

# Summary

### ID

NL-OMON43303

**Source** ToetsingOnline

Brief title Yellow fever vaccination follow-up after 10 years

# Condition

• Viral infectious disorders

**Synonym** immune response to yellow fever vaccination

#### **Research involving** Human

### **Sponsors and support**

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

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### Intervention

Keyword: immune response, intradermal, vaccination, yellow fever

### **Outcome measures**

#### **Primary outcome**

protective immune response, measured in neutralizing antibodies, 10 years after

yellow fever vaccination (i.d. administration compared to s.c.)

#### Secondary outcome

none

# **Study description**

#### **Background summary**

In order to protect the large susceptible population in subsaharan Africa against yellow fever, in the scope of the outbreak in Angola which started in January 2016, mass vaccination campaigns have been conducted. Nevertheless, the yellow fever vaccine stockpile had been depleted twice since the start of the outbreak, which calls for creative solutions to augment this stockpile.

Our research published in 2008 showed a non-inferior immune response (measured in neutralizing antibodies) to 1/5th dose of yellow fever vaccine injected intradermally, compared to the standard subcutaneous dose.

Based on these results, the WHO advised to vaccinate with a fractional dose (1/5the of the standard dose) in the following vaccination campaign in Kinshasa. As no long term results are available on the immune response after interdermal yellow fever vaccination, we propose to measure the neutralizing antibodies response in the participants of the trial 10 years ago.

#### **Study objective**

To investigate the long term (ten years) protective immune response to fractional yellow fever vaccination (1/5th of the standard dose, injected intradermally), compared to the standard subcutaneous vaccination

#### Study design

- follow-up of a previously conducted trial (randomized, controlled, single centre study)

- one blood sampling (8cc) for serology

#### Study burden and risks

- no risk (only 1 blood sample)

- benefit: knowledge on the long term protection to intradermal fractioned yellow fever vaccination, which is directly applicable to the current mass vaccination campaign in subsaharan Africa in order to protect a large susceptible population against yellow fever

# Contacts

#### Public

Academisch Medisch Centrum

Albinusdreef 2 Leiden 2300 RC NL **Scientific** Academisch Medisch Centrum

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

# **Inclusion criteria**

Participants of the yellow fever vaccination study performed 10 years ago

# **Exclusion criteria**

standard yellow fever vaccination after participating in the trial ten years ago

# Study design

## Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2017
Enrollment:	155
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	15-02-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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# **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** CCMO ID NL58757.058.16

# **Study results**