

# Comparison between immune response to different modes of vaccination: intradermal and subcutaneous yellow fever vaccination

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| <b>Submission date</b><br>20/12/2005   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>20/12/2005 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>02/09/2019       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

Comparison between immune response to different modes of vaccination: intradermal and subcutaneous yellow fever vaccination

## Study objectives

Intradermal yellow fever vaccination with a reduced dose will induce a sufficient protective immunological response comparable to the response elicited by subcutaneous yellow fever vaccination.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Yellow Fever

## Interventions

Subcutaneous of intradermal yellow fever vaccination.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Yellow fever vaccination

**Primary outcome measure**

1. Protective humoral immune response
2. For first time vaccinees measured 4 and 8 weeks post-vaccination, for revaccinees measured 2 weeks post-vaccination.
3. All sera will be analysed by ELISA, Immunofluorescence and plaque reduction assay.

**Secondary outcome measures**

Adverse events measured for three weeks post-vaccination by keeping a diary, viremia measured 5 days post-vaccination by RT-PCR.

**Overall study start date**

15/06/2005

**Completion date**

15/06/2006

**Eligibility****Key inclusion criteria**

Healthy volunteers, greater than 18 years (previously and not previously vaccinated with yellow fever vaccine)

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

120

**Total final enrolment**

155

**Key exclusion criteria**

1. Pregnancy
2. Diabetes mellitus
3. Use of immunomodulating medication, e.g. corticosteroids
4. Cytostatica
5. Use of chloroquine

**Date of first enrolment**

15/06/2005

**Date of final enrolment**

15/06/2006

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Leiden University Medical Centre (LUMC)**

Leiden

Netherlands

2333 ZA

## **Sponsor information**

**Organisation**

Leiden University Medical Centre (LUMC) (Netherlands)

**Sponsor details**

Albinusdreef 2

P.O. Box 9600

Leiden

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**Sponsor type**

University/education

**Website**

<http://www.lumc.nl/>

**ROR**

<https://ror.org/027bh9e22>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Leiden University Medical Centre (LUMC) (The Netherlands) - Department of Infectious Diseases

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 23/04/2008   |            | Yes            | No              |
| <a href="#">Results article</a> | results | 04/12/2018   | 02/09/2019 | Yes            | No              |