

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/09/2019	Condition category 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

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Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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?
Results article	results	23/04/2008		Yes	No
Results article	results	04/12/2018	02/09/2019	Yes	No