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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27364

Source
Nationaal Trial Register

Brief title
N/A

Health condition

(Prevention of) yellow fever.

Sponsors and support

Primary sponsor: Leiden University Medical Center, dpt. of Infectious Diseases
Source(s) of monetary or material Support: Leiden University Medical Center, dpt. of Infectious Diseases

Intervention

Outcome measures

Primary outcome

Protective humoral immune response.

For first time vaccinees measured 4 and 8 weeks post-vaccination, for revaccinees measured 2 weeks post-vaccination.

All sera will be analysed by ELISA, Immunofluorescence and plaque reduction assay.

Secondary outcome

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

Study description

Background summary

Comparison between effectivity of different methods of vaccination; antibody response to intradermal and subcutaneous yellow fever vaccination, measured by ELISA, IF and plaque reduction assay.

Furthermore adverse events will be studied by keeping a diary, and viremia will be measured in a subgroup of the first time vaccinees and the revaccinees.

Study objective

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.

Study design

N/A

Intervention

Subcutaneous of intradermal yellow fever vaccination.

Contacts

Public
Leiden University Medical Center (LUMC),

P.O. Box 9600
A.H.E. Roukens
Albinusdreef 2
Leiden 2300 RC
The Netherlands
Scientific
Leiden University Medical Center (LUMC),
P.O. Box 9600
A.H.E. Roukens
Albinusdreef 2
Leiden 2300 RC
The Netherlands

Eligibility criteria

Inclusion criteria

Healthy volunteers, >18yrs (previously and not previously vaccinated with yellow fever vaccine).

Exclusion criteria

1. Pregnancy;

2. Diabetes mellitus;

3. Use of immunomodulating medication e.g. corticosteroids;

4. Cytostatica;

5. Use of chloroquine.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2005
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2005
Application type:	First submission

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
NTR-new	NL194
NTR-old	NTR231
Other	: N/A
ISRCTN	ISRCTN46326316

Study results

Summary results
PLoS ONE. 2008 Apr 23;3(4):e1993.