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

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr A.H.E. Roukens

Contact details
Leiden University Medical Centre (LUMC)
Albinusdreef 2, C5-P
Leiden
Netherlands
2333 ZA
-
a.h.e.roukens@lumc.nl

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