ISRCTN46326316 https://doi.org/10.1186/ISRCTN46326316

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 02/09/2019	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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2300 RC

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