Immunity induced by Yellow Fever vaccination in the elderly (60 years or OLDer) traveller

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
05/09/2007		☐ Protocol		
Registration date 05/09/2007	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
07/10/2021	Infections and Infestations			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LUMC

Study information

Scientific Title

Immunity induced by Yellow Fever vaccination in the elderly (60 years or OLDer) traveller

Acronym

YFOLD

Study objectives

The induction of immunity might be slower in older persons than in younger individuals. This could influence the occurrence of adverse events induced by the vaccine.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomized active-controlled parallel-group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Yellow Fever vaccination

Interventions

Yellow fever vaccination (only an extra intervention in control group), blood drawing and urine sampling.

Intervention Type

Biological/Vaccine

Phase

Not Applicable

Primary outcome measure

- 1. Neutralizing antibodies
- 2. Yellow fever viremia

Secondary outcome measures

- 1. Presence of yellow fever virus proteins in urine samples
- 2. Adverse events

Overall study start date

01/10/2007

Completion date

01/10/2008

Eligibility

Key inclusion criteria

Elderly group:

- 1. Age of 60 years or older
- 2. Indication for yellow fever vaccination according to Dutch travel guidelines

Control group: age under 60 years

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

60

Total final enrolment

58

Key exclusion criteria

- 1. Immune suppression due to disease or medication
- 2. Pregnancy

Date of first enrolment

01/10/2007

Date of final enrolment

01/10/2008

Locations

Countries of recruitment

Netherlands

Study participating centre Leiden University Medical Centre (LUMC)

Leiden Netherlands 2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details

Department of Infectious Diseases P.O. Box 9600 Leiden Netherlands 2300 RC +31 (0)71 526 9111 a.h.e.roukens@lumc.nl

Sponsor type

Hospital/treatment centre

Website

http://www.lumc.nl/english/start_english.html

ROR

https://ror.org/027bh9e22

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands)

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		07/12/2011	07/10/2021	Yes	No