Long-term protection after primary yellow fever vaccination in elderly persons (60 years or older at the time of primary vaccination)

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The results of this research contribute significantly to the field of Travel Medicine, especially for elderly travelers who have been vaccinated with YF-17D at 60 years or older, and who are planning to visit a yellow fever endemic country in the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON48529

Source
ToetsingOnline

Brief title
Long-term protection after yellow fever vaccination at old age (GKOUD10)

Condition

- Viral infectious disorders

Synonym
protection after vaccination

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Elderly, Vaccination, Waning immunity, Yellow fever

Outcome measures

Primary outcome

The primary endpoint is the percentage of participants with protective YFVNA titers in the elderly group compared to the younger group, ten years after primary vaccination.

Secondary outcome

The secondary endpoint is the geometrical mean titre of yellow fever neutralizing antibodies in each study group.

Study description

Background summary

The objective of this project is to assess the persistence of protective yellow fever virus neutralizing antibodies (YFVNA) titers, ten years after a primary yellow fever vaccination in travelers of sixty years and older at the time of vaccination.
In 2008-2009 we performed a controlled cohort clinical trial in 58 travellers comparing antibody response and viremia after primary vaccination with live attenuated 17D yellow fever vaccine (YF-17D) in elderly travelers (60-81 years at vaccination, N = 28) and young volunteers (18-28 years at vaccination, N =30).

The elderly persons had a delayed antibody response and higher viremia compared to the control group. In all cases the World Health Organization (WHO) standard of seroprotection (*80% virus neutralization at 1:10 serum dilution) was reached after 30 days [1]. This result led us to the hypothesis that with older age, a weaker initial immune response to yellow fever vaccine allows the attenuated virus to cause higher viraemia levels, which may increase the risk of developing SAEs. This may be one piece in the puzzle of the pathophysiology of YEL-AVD, the vaccine-induced yellow fever.

In 2016, the WHO stipulated that the standard yellow fever vaccination induces lifelong protection, and that a booster vaccination is no longer needed after 10 years. [2] Whether this also applies to elderly vaccinated persons has never been investigated, and is a relevant question to be addressed in the light of waning immunity with age, and an increasing elderly travel population.
Our hypothesis is that vaccine-induced lifelong immunity after one standard YF-17D vaccination is not necessarily applicable to individuals of 60 years and older.

Study objective

The results of this research contribute significantly to the field of Travel Medicine, especially for elderly travelers who have been vaccinated with YF-17D at 60 years or older, and who are planning to visit a yellow fever endemic country in the nearby future. In addition, the results will have important implications for persons of 60 years and older who are living in yellow fever endemic areas.

If this follow-up study shows that elderly persons do not confer long-term protection (defined as 10 years) after standard YF-17D vaccination, measures should be taken to protect them if they are at risk for new exposure to wild type yellow fever virus.

Study design

This is a follow-up study of the initial study cohort of 2008-2009 [1]. All participants from the original study population gave permission to be contacted again in the future. These participants will be invited to provide a serum sample for serological testing. Travel history, documented flavivirus infections or vaccinations in the past ten years will be recorded. Participants will be excluded if they have been revaccinated against yellow fever after the initial trial. YFVNA will be determined by plaque reduction neutralization test (PNRT). PRNT will be performed by the Laboratory of Virology of the Leiden University Medical Center (LUMC).

Samples size calculation is not applicable as we will not be able to include more participants than those who participated in the initial trial. We have already contacted most participants and they are all willing to participate.

Study burden and risks

Negligible risk (only one venous puncture)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participation in the clinical vaccine trial in 2008-2009 (GKOUD)

Exclusion criteria

Receipt of an extra yellow fever vaccination after participation in the GKOUD trial

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2019
Enrollment:	58
Type:	Actual

Ethics review

Approved WMO

Date:	24-10-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL68798.058.19

Study results