

Follow-up of the immune response ten years after intradermal or subcutaneous yellow fever vaccination

Published: 15-02-2017

Last updated: 14-04-2024

To investigate the long term (ten years) protective immune response to fractional yellow fever vaccination (1/5th of the standard dose, injected intradermally), compared to the standard subcutaneous vaccination

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

Summary

ID

NL-OMON43303

Source

ToetsingOnline

Brief title

Yellow fever vaccination follow-up after 10 years

Condition

- Viral infectious disorders

Synonym

immune response to yellow fever 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: immune response, intradermal, vaccination, yellow fever

Outcome measures

Primary outcome

protective immune response, measured in neutralizing antibodies, 10 years after

yellow fever vaccination (i.d. administration compared to s.c.)

Secondary outcome

none

Study description

Background summary

In order to protect the large susceptible population in subsaharan Africa against yellow fever, in the scope of the outbreak in Angola which started in January 2016, mass vaccination campaigns have been conducted. Nevertheless, the yellow fever vaccine stockpile had been depleted twice since the start of the outbreak, which calls for creative solutions to augment this stockpile.

Our research published in 2008 showed a non-inferior immune response (measured in neutralizing antibodies) to 1/5th dose of yellow fever vaccine injected intradermally, compared to the standard subcutaneous dose.

Based on these results, the WHO advised to vaccinate with a fractional dose (1/5th of the standard dose) in the following vaccination campaign in Kinshasa. As no long term results are available on the immune response after intradermal yellow fever vaccination, we propose to measure the neutralizing antibodies response in the participants of the trial 10 years ago.

Study objective

To investigate the long term (ten years) protective immune response to fractional yellow fever vaccination (1/5th of the standard dose, injected intradermally), compared to the standard subcutaneous vaccination

Study design

- follow-up of a previously conducted trial (randomized, controlled, single centre study)
- one blood sampling (8cc) for serology

Study burden and risks

- no risk (only 1 blood sample)
- benefit: knowledge on the long term protection to intradermal fractionated yellow fever vaccination, which is directly applicable to the current mass vaccination campaign in subsaharan Africa in order to protect a large susceptible population against yellow fever

Contacts

Public

Academisch Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL

Scientific

Academisch Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Participants of the yellow fever vaccination study performed 10 years ago

Exclusion criteria

standard yellow fever vaccination after participating in the trial ten years ago

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2017
Enrollment:	155
Type:	Actual

Ethics review

Approved WMO	
Date:	15-02-2017
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	NL58757.058.16

Study results