Immunological effects of BCG on vaccination with the yellow fever vaccine.

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1) To determine whether vaccination with yellow fever results in a higher cytokine response upon restimulation in vitro with non-related infectious pathogens, compared to the response before the vaccination.2) To determine whether BCG vaccination...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON40902

Source
ToetsingOnline

Brief title
Immunological effects of BCG on vaccination with the yellow fever vaccine.

Condition

- Ancillary infectious topics

Synonym
Immune modulation, modulation of the immune system

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: BCG, Immunology, Yellow Fever

Outcome measures

Primary outcome

According to the objectives:

1) Increase of in vitro cytokine production of PBMCs after stimulation with different pathogens compared to before yellow fever vaccination. (only placebo group)

2) Yellow fever antibody titers, Th-immune responses, and proinflammatory cytokine production in BCG versus placebo vaccinated volunteers.

3) The rate of clearance of the circulating yellow fever vaccine virus in BCG- versus placebo-vaccinated volunteers.

Secondary outcome

n.v.t.

Study description

Background summary

The live attenuated Bacillus Calmette-Guerin (BCG) vaccine protects against extrapulmonary infection with Mycobacterium tuberculosis and leprosy. It has been shown that vaccination with BCG, just as other live vaccines as measles, leads to nonspecific protective effects, e.g. reduced infant mortality as a result of less severe infections, stimulation of the immune system in patients with bladder cancer and higher cytokine production upon restimulation of monocytes with non-related infectious pathogens in vitro. For yellow fever (YF), which is also a live attenuated vaccine, no immunological confirmation has been shown yet that it is also able to raise nonspecific protection. Also whether the BCG vaccine can influence the course of viremia with the yellow fever vaccine, or boost the yellow fever vaccine, are questions that need to be

answered.

Study objective

1) To determine whether vaccination with yellow fever results in a higher cytokine response upon restimulation in vitro with non-related infectious pathogens, compared to the response before the vaccination.
2) To determine whether BCG vaccination can induce a better antibody and cellular response of the yellow fever vaccine.
3) To determine whether BCG vaccination status has an effect on the clearance of the yellow fever virus in vivo.

Study design

Explorative randomised placebo controlled trial.

Study burden and risks

There is no known direct benefit for the volunteers to participate in the trial. The risks are negligible. Vaccination can cause pain and scarring at the site of injection, just as fever, gastrointestinal symptoms and headache. Local hematoma formation can occur at the site of the blood drawing. This will be minimized by the blood collection by experienced persons. Volunteers have to spend 7 or 8 short visits.

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

Healthy
18-55 years old

Exclusion criteria

Exposed to TBC, BCG or yellow fever (vaccine), use of mediation

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2015
Enrollment:	30

Type:	Actual

Ethics review

Approved WMO Date:	09-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL50160.091.14

Study results

Date completed:	08-02-2016
Actual enrolment:	30