

ROLE OF BCG VACCINATION AS BOOSTER ON SALMONELLA TYPHI VACCINE

Published: 17-04-2012

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To examine the effect of BCG as a booster vaccine on salmonella typhi Vi polysaccharide vaccination

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON37465

Source

ToetsingOnline

Brief title

BCG-TFV1

Condition

- Bacterial infectious disorders

Synonym

efficacy of vaccine, vaccination respons

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

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

Intervention

Keyword: BCG vaccination, salmonella typhi vaccination

Outcome measures

Primary outcome

The following parameters are compared between two groups: cytokine production and antibody titers against salmonella typhi Vi antigen on different time points after vaccination.

Secondary outcome

Gene polymorphisms are analyzed and correlated with innate immunity function

Study description

Background summary

The live attenuated Bacillus Calmette-Guerin (BCG) vaccine protects against Mycobacterium tuberculosis and leprosy. It is also used as booster vaccine to improve the immunogenicity against other vaccines. We hypothesize that BCG vaccination 14 days before salmonella typhi Vi polysaccharide vaccine improves the effect of this vaccine.

Study objective

To examine the effect of BCG as a booster vaccine on salmonella typhi Vi polysaccharide vaccination

Study design

observational study between 2 groups (with or without BCG vaccination)

Study burden and risks

There is no direct benefit to the participating subjects but it is expected that these results will potentially lead to a novel approach to vaccine strategies for travelers. The risks are negligible, the only risk involving local hematoma formation at the site of the blood drawing. This will be minimized by the blood collection by experienced persons.

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 medical students who are scheduled to go on clinical rotation in developing countries and need to be vaccinated with BCG and typhoid fever vaccine

Exclusion criteria

Subjects should not come from a Salmonella typhi endemic country and are not allowed to use any medication except oral contraception drugs.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	25-07-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO	
Date:	17-04-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	04-02-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	15-01-2015
Application type:	Amendment
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	NL39957.091.12