Immune repons induced by vaccination with BCG

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mycobacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON37373

Source
ToetsingOnline

Brief title
BCG-trial

Condition

- Mycobacterial infectious disorders

Synonym
Immuunresponse by BCG vaccination Tuberculosis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: afdelingsfonds;interne verrekening

Intervention

Keyword: BCG, Tuberculosis, Vaccination

Outcome measures

Primary outcome

Vaccine induced changes in the antigen-specific immune response and in

BCG-specific biomarkers following vaccination with BCG.

Secondary outcome

Not applicable

Study description

Background summary

Tuberculosis is a growing global health problem. The only available vaccine is bacille calmette-guérin (BCG). Each year BCG is given to millions of childeren around the world, particularly in tuberculosis endemic countries. It protects young childeren from severe forms of tuberculosis, but it is of limited value in adults. We hypothesize that the antigen expression profile of BCG during intradermal vaccination is different from that of Mycobacterium tuberculosis. The partial failure of BCG may be related to this difference.

Study objective

Primary objective is to characterize the anti-mycobacterial immune responses during vaccination with live-attenuated M. Bovis BCG Danish strain 1331, in order to provide a framework for using biomarkers in future TB vaccine trials. Secondary objective is to evaluate whether biomarkers, specific for BCG can be detected in the circulation and in the urine following vaccination. Such profiles could be useful as markers in future TB vaccine trials and may also be a first step in developing these techniques to diagnose latent tuberculosis infection.

Study design

Healthy adult individuals will be vaccinated with BCG and temporal changes in T cell responses against mycobacterial antigens will be monitored in vitro. The research will be conducted by the department of Infectious Diseases at the

Leiden University Medical Center.

Intervention

BCG vaccine SSI (Danish strian 1331; RVG number 17661)

Study burden and risks

Burden for study participants:
The total average duration of the visits to the study centrum (LUMC) is approximately 4 hours, divided over 10 visits over a period of 52 weeks. During the visits two tuberculin skintest will be performed, one vaccination with BCG and 9 vena punctures will be perfomed in which participants will be required to donate a maximum of 52.5 ml of venous blood per visit, a total of 448 ml of venous blood during the entire study and 5 urine samples for the laboratory analyses.

Potential risks: BCG is a registered vaccine which is widely used throughout the world. It is a live-attenuated vaccine and is contraindicated for persons with impaired cellular immunity. In view of our outcome measures BCG will also not be given to persons with a positive tuberculin reaction or a positive Quantiferon-TB Gold In-Tube blood test. In case of a positive Mantoux test and/or Quantiferon-Tb Gold In-Tube test at week-1, the subject will be counseled by the investigator. The "Tuberculosebestrijding of GGD Hollands Midden"will be contacted. If the investigator and/or the GGD think it necessary, the participant will be refered to this department for further counseling and management.

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;Age 18-55 year;Naieve Tuberculose volunteers (negative TST and negative QFN-test)

Exclusion criteria

History of TB disease or treatment;BCG vaccination;HIV-positive;Pregnancy / breastfeeding

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bacillus Calmette-Guérin

Ethics review

Approved WMO Date:	27-04-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-06-2012
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
EudraCT	EUCTR2011-005653-31-NL
CCMO	NL39528.058.12