Effects of BCG vaccination on immunological characteristics of hematopoetic stem cells: an explorative study

Published: 23-06-2016
Last updated: 19-03-2025

To examine the effect of BCG vaccination on the composition and function of the bone marrow.

Ethical review	Approved WMO
Status	Completed
Health condition type	Immune disorders NEC
Study type	Interventional

Summary

ID

NL-OMON43468

Source
ToetsingOnline

Brief title
Effects of BCG on HSC

Condition

- Immune disorders NEC
- Ancillary infectious topics

Synonym
BCG vaccine, tuberculosis vaccine

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: NWO

Intervention

Keyword: BCG, bone marrow, hematopoetic stem cells, HSC

Outcome measures

Primary outcome

Cellular composition of the bone marrow

Ex vivo differentiation of hematopoetic stem and progenitor cells

Ex vivo cytokine responses of hematopoetic stem and progenitor cells

Secondary outcome

Ex vivo cytokine production of PBMCs and monocytes

Gene expression profiles of hematopoetic stem cells and peripheral monocytes

Epigenetic profiles relating to immune function of hematopoetic stem cells and

peripheral monocytes

Cellular metabolism of hematopoetic stem cells and peripheral monocytes

Study description

Background summary

The Bacillus Calmette-Guerin (BCG) vaccine not only protects aginst mycobacterium tuberculosis, but has also been shown to reduce morbidity and mortality caused by non-related infections. This effect is likely due to non-specific, epigenetically mediated immunomodulatory effects, at least in part on the inate immune system, but the precise mechanism of the protective effect of BCG on non-mycobacterial infections is not fully known. The effects of BCG of the innate immune system last up to 3 months to 1 year and cannot be explained by a direct effect on the effector cells of the innate immune system.

During the process of hematopoesis mature peripheral blood cells are produced from hematopoetic stem and progenitor cells in the bone marrow. Stimulation of hematopoetic stem cells can lead to functionally different progenitor cells.

BCG vaccination could possibly lead to changes in hematopoetic stem cells which lead to the observed long term changes in the innate immune system after BCG vaccination.

Study objective

To examine the effect of BCG vaccination on the composition and function of the bone marrow.

Study design

A prospective, randomized, placebo controlelled, open-label, blinded end-point trial. Healthy volunteers will be randomized in 2 groups. Group 1 will be vaccinated with placebo, group 2 will be vaccinated with BCG. Before vaccination and two weeks after vaccination blood will be drawn and bone marrow aspiration will be performed. Volunteers allocated to the BCG group will undergo a FDG-PET-CT scan before and three months after vaccination

Intervention

Group 1: placebo vaccination.
Group 2: BCG vaccination.

Study burden and risks

BCG vaccine is a registered vaccine that has been shown to be safe. Mild side effects such as local skin reactions are possible. Bone marrow aspiration is a safe procedure, that is generally well tolerated if performed by experienced personnel. Both blood donation and bone marrow aspiration will only be performed by experienced personnel in this study.
There are no direct benefits to participants apart from the benefit conferred by BCG vaccination in participants who plan on going abroad for medical work, but these results will potentially lead to novel strategies to optimize vaccination policies.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6500HB
NL
Scientific

Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6500HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age>18
Healthy

Exclusion criteria

Use of systemic medication other than oral anti-contraceptive drugs
Vaccination within 3 months prior to study period
History of haematological disease
History of malignancy
Medical history of disease associated with immune deficiency
Previous BCG vaccination
Acute illness within 2 months prior to start of study
Pregnancy
Anaemia or other deviations in a complete blood count
NSAID within the last 2 weeks
History of claustrophobia
Fastened glucose >8mmol/l

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-12-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	23-06-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-12-2016
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

ID: 24361
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL55825.091.15
OMON	NL-OMON24361