Influence of BCG vaccine as a booster for TDaP-IPV vaccination

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To examine the effect of BCG as an adjuvant on DTP vaccination, and to investigate the non-specific training effects of BCG and DTP, alone and in combination, on the innate immune system.

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

Summary

ID

NL-OMON40745

Source
ToetsingOnline

Brief title
Influence of BCG

Condition

- Immune disorders NEC
- Ancillary infectious topics

Synonym
Pertussis, Whooping cough

Research involving
Human

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: NWO

Intervention

Keyword: BCG, booster, TDaP-IPV

Outcome measures

Primary outcome

Comparison of pertussis-specific antibody and T-cell responses, as well as gene transcription between BCG, TDaP-IPV and BCG+TDaP-IPV vaccinated groups.

Comparison of cytokine responses to unrelated antigens and/or pathogens before and after BCG, TDaP-IPV or BCG+TDaP-IPV vaccination.

Secondary outcome

Epigenetic markers associated with immune function.

Study description

Background summary

The Bacillus Calmette-Guerin (BCG) vaccine not only protects against 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 immunomodulatory effects, at least in part on the innate immune system. Additionally, BCG has been shown to improve immunogenicity of other vaccinations.
In contrast, whilst the diphtheria-tetanus-pertussis (DTP) combination vaccine protects against infection with Bordetella pertussis, Clostridium tetani and Corynebacterium diphtheria, it has also been associated with increased mortality due to unrelated infections, particularly in girls in high-mortality countries.
Although widespread DTP vaccination has initially reduced pertussis mortality, the disease has persisted and recently resurged in a number of countries with highly vaccinated populations, including the Netherlands. This has been partially attributed to the switch from a whole-cell vaccine (which is still being used in low-income countries) to a more defined acellular pertussis vaccine, which only protects for a limited period (5-8 years). Strategies to improve the efficacy of pertussis vaccination are therefore urgently required.

Study objective

To examine the effect of BCG as an adjuvant on DTP vaccination, and to investigate the non-specific training effects of BCG and DTP, alone and in combination, on the innate immune system.

Study design

Healthy volunteers will be divided in three groups. Group 1 will receive BCG first, followed by Boostrix Polio (diphteria, tetanus, pertussis, poliomyelitis) 3 months later. Group 2 will receive BCG and Boostrix Polio simultaneously. Group 3 will first receive Boostrix polio, followed by BCG 3 month later. Blood will be taken before and at different timepoints after vaccination.

Intervention

BCG vaccination
Vaccination with Boostrix Polio

Study burden and risks

There is no direct benefit to the study participants but these results will potentially lead to novel strategies to optimize vaccinations. The risks for participants are negligible, with the only expected risks being minor side-effects from vaccination and local hematoma forming at the site of venepuncture. This will be minimized by the performance of these procedures by experienced personnel.

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 adults

Exclusion criteria

Systemic medication other oral contraceptives. Diseases resulting in immunodeficiency. Previous BCG vaccination. Pregnancy.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	29-01-2015
Enrollment:	51
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-04-2015
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	NL49814.091.14