

# BACILLUS CALMETTE-GUÉRIN VACCINATION TO PREVENT SERIOUS RESPIRATORY TRACT INFECTION AND COVID-19 IN VULNERABLE ELDERLY -\* AN ADAPTIVE RANDOMIZED CONTROLLED TRIAL

Published: 21-08-2020

Last updated: 17-01-2025

To determine the impact of BCG vaccination on the incidence of clinically relevant respiratory infections or COVID-19 in vulnerable older adults.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Viral infectious disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON49683

### Source

ToetsingOnline

### Brief title

BCG-PRIME

### Condition

- Viral infectious disorders

### Synonym

COVID-19, SERIOUS RESPIRATORY TRACT INFECTION

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

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

## Intervention

**Keyword:** BCG, COVID-19, Elderly, RespiratoryTract

## Outcome measures

### Primary outcome

The trial has an adaptive primary endpoint. Based on accrual of the two endpoints , the primary endpoint will be either a) clinically relevant respiratory tract infections requiring medical intervention, potentially including COVID-19, or b) laboratory-confirmed and/or physician-diagnosed COVID-19. The other will be declared secondary endpoint

### Secondary outcome

SARS-CoV-2 infection (including asymptomatic infections), influenza infection, Acute Respiratory Infection, ARI-related hospital admission, COVID-19 related hospital admission, pneumonia, mental, physical and social functioning, serious adverse events and adverse events.

## Study description

### Background summary

On March 11 2020 the World Health Organization (WHO) declared the coronavirus (SARS-CoV-2) outbreak a pandemic. Worldwide, the number of confirmed cases continues to rise, leading to significant morbidity and mortality. In the Netherlands, although the incidence is currently low due to social distancing measures, some experts anticipate a new epidemic peak. Although individuals of any age can acquire SARS-CoV-2, adults of middle and older age are at highest risk for developing severe COVID-19 disease. Moreover, recent reports

demonstrate that mortality rates rise significantly among patients 60 years and older. Therefore, strategies to prevent SARS-CoV-2 infection or to reduce its clinical consequences in vulnerable populations are urgently needed. Bacille Calmette-Guérin (BCG) vaccine not only protects against tuberculosis, but has also been shown to induce protection against various respiratory infections, including those with a viral aetiology. We hypothesize that BCG vaccination may reduce clinically relevant respiratory tract infections requiring medical intervention, including COVID-19, in older adults discharged from the hospital.

## **Study objective**

To determine the impact of BCG vaccination on the incidence of clinically relevant respiratory infections or COVID-19 in vulnerable older adults.

## **Study design**

A multi-centre double-blind randomized placebo-controlled trial

## **Intervention**

Participants will be randomized between intracutaneous administration of BCG vaccine (Danish strain 1331) or placebo (0.1ml 0.9% NaCl) in a 1:1 ratio

## **Study burden and risks**

Burden: Vaccination could cause local pain, suppuration and scarring at the site of injection. The local reaction after BCG vaccination is usually mild and self-limiting

Risks: . Less common are fever and headache after vaccination and, if they occur, they are typically mild. Enlargement of the axillary lymph nodes may occasionally occur after vaccination but will usually regress spontaneously after a few months

## **Contacts**

### **Public**

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### **Scientific**

Karma Oncology

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Heidelberglaan 100  
Utrecht 3508 AB  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

criteria:

\* Age ≥60 years

\* Meeting at least one of the following criteria:

a) Having a chronic somatic disease\*

b) Having undergone major surgery\*\*

c) Planned to be discharged from the hospital or discharged from the hospital less than 6 weeks ago; a hospital admission is defined as an overnight stay.

Departments of interest are those that in the opinion of the principle investigator admit mostly vulnerable elderly and include but are not limited to: cardiology, pulmonology, internal medicine, neurology.

d) Attending the thrombosis care service

\* Written informed consent

### Exclusion criteria

\* Fever (>38 °C) within the past 24 hours

\* Suspicion of current active viral or bacterial infection; the requirement to finish an antibiotic course upon discharge is not an exclusion criterion when the infection is controlled in the opinion of the attending physician

\* Vaccination with live vaccine in the past four weeks or planned vaccination with live vaccine during the next four weeks

\* Severely immunocompromised participants

\* Known history of a positive Mantoux or active TB enHistory of documented

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## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	07-09-2020
Enrollment:	7000
Type:	Actual

### Medical products/devices used

Product type:	Medicine
Brand name:	Bacillus Calmette-Guérin (BCG),BCG vaccin SSI

## Ethics review

Approved WMO	
Date:	21-08-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	27-08-2020
Application type:	First submission
Review commission:	METC NedMec

Approved WMO	
Date:	28-08-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	22-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	26-10-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	17-06-2021
Application type:	Amendment
Review commission:	METC NedMec

## 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	EUCTR2020-003470-47-NL
CCMO	NL74730.041.20

## Study results

Date completed:	22-07-2021
Results posted:	08-09-2022
Actual enrolment:	6112

**First publication**  
14-07-2022