# REDUCING HOSPITAL ADMISSION OF ELDERLY IN SARS-CoV-2 PANDEMIC VIA THE INDUCTION OF TRAINED IMMUNITY BY BACILLUS CALMETTE-GUÉRIN VACCINATION, A RANDOMIZED CONTROLLED TRIAL

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We hypothesize that BCG vaccination may reduce hospital admission and improve the clinical course of symptoms of elderly people during the SARS-CoV-2 outbreak.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON19909

**Bron**
Nationaal Trial Register

**Verkorte titel**
BCG-CORONA-ELDERLY

**Aandoening**

COVID-19

### Ondersteuning

**Primaire sponsor:** Radboudumc
**Overige ondersteuning:** No

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

• SARS-CoV-2 related hospital admission

# Toelichting onderzoek

### Achtergrond van het onderzoek

On March 11 2020 the World Health Organization (WHO) declared the coronavirus (SARS-CoV-2) outbreak a pandemic. The number of confirmed cases continues to rise, leading to significant morbidity and mortality worldwide. Although individuals of any age can acquire SARS-CoV-2, adults of middle and older age are most commonly affected. 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 elderly are desperately needed. Bacillus 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, leading to significant reductions in morbidity and mortality. We hypothesize that BCG vaccination may reduce hospital admission and improve the clinical course of symptoms of elderly people during the SARS-CoV-2 outbreak.
Objective: Primary objective: to reduce SARS-CoV-2-related hospital admission of community dwelling older persons (≥ 60 years of age). Secondary objective: to reduce the incidence of health symptoms, the duration of hospital admission, hospital or ICU admission for any reason, or death in community dwelling older persons during the SARS-CoV-2 outbreak.
Study design: A placebo-controlled adaptive multi-centre randomized controlled trial.
Study population: Elderly people (≥ 60 years of age).
Intervention: Participants will be randomized between intracutaneous administration of BCG vaccine or placebo in a 1:1 ratio.
Main study parameters/endpoints: Primary endpoint: SARS-CoV-2 related hospital admission. Secondary endpoints: incidence of symptoms of infectious disease, hospital admission for any reason, duration of hospital admission, SARS-CoV-2 infection, Intensive Care admission, and death.

### Doel van het onderzoek

We hypothesize that BCG vaccination may reduce hospital admission and improve the clinical course of symptoms of elderly people during the SARS-CoV-2 outbreak.

### Onderzoeksopzet

6 months

**Onderzoeksproduct en/of interventie**

BCG-vaccine

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adult (≥ 60 years)

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Fever (>38 ºC) within the past 24 hours
• Suspicion of current active viral or bacterial infection
• Expected vaccination during the first three months of the study period
• Severely immunocompromised subjects. This exclusion category comprises: a) subjects with known infection by the human immunodeficiency virus (HIV-1); b) neutropenic subjects with less than 500 neutrophils/mm3; c) subjects with solid organ transplantation; d) subjects with bone marrow transplantation; e) subjects under chemotherapy; f) subjects with primary

immunodeficiency; g) severe lymphopenia with less than 400 lymphocytes/mm3; h) treatment with any immunosuppressant drugs such as anti-cytokine therapies, and treatment with oral or intravenous steroids defined as daily doses of 10mg prednisone or equivalent for longer than 3 months, or probable use of oral or intravenous steroids in the following four weeks
• Active solid or non-solid malignancy or lymphoma within the prior two years
• Active participation in another research study that involves BCG administration

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Placebo |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 16-04-2020 |
| Aantal proefpersonen: | 1600 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 22-04-2020 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49238
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8547 |
| CCMO | NL73430.091.20 |
| OMON | NL-OMON49238 |

# Resultaten