# BCG vaccination for healthcare workers in SARS-CoV-2 pandemic

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BCG vaccination may induce (partial) protection against susceptibility to and/or severity of SARS-CoV-2 infection. This will lead to reduced workplace absenteeism under health care workers taking care of patients with COVID-19

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

## Samenvatting

### ID

NL-OMON27106

**Bron**
Nationaal Trial Register

**Verkorte titel**
BCGcorona

**Aandoening**

SARS-CoV-2, COVID19

### Ondersteuning

**Primaire sponsor:** University Medical Centre Utrecht
**Overige ondersteuning:** University Medical Centre Utrecht

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Number of days of unplanned absenteeism for any reason

# Toelichting onderzoek

### Achtergrond van het onderzoek

RATIONALE: SARS-CoV-2 spreads rapidly throughout the world. A large epidemic in the Netherlands would seriously challenge the available hospital capacity, and this would be augmented by absenteeism of healthcare workers (HCW). Strategies to prevent absenteeism of HCW are, therefore, desperately needed to safeguard continuous patient care. Bacille Calmette-Guérin (BCG) is a vaccine against tuberculosis, with protective non-specific effects against other respiratory tract infections in in vitro and in vivo studies, and reported significant reductions in morbidity and mortality. We hypothesize that BCG vaccination can reduce HCW absenteeism during the epidemic phase of SARS-CoV-2.
OBJECTIVES: Primary objective: To reduce absenteeism among HCW with direct patient contacts during the epidemic phase of COVID19. Secondary objective: To reduce hospital admission, ICU admission or death in HCW during the epidemic phase of COVID19.
STUDY DESIGN: A placebo-controlled adaptive multi-centre randomized controlled trial.
STUDY POPULATION: HCW with direct patient contacts, defined as nurses and physicians working at emergency rooms and wards where COVID-infected patients are treated.
INTERVENTION: Participants will be randomized between intracutaneous administration of BCG vaccine or placebo in a 1:1 ratio.
MAIN STUDY PARAMETERS/ENDPOINTS: Primary endpoint: number of days of (unplanned) absenteeism for any reason. Secondary endpoints: number of days of (unplanned) absenteeism because of documented SARS-CoV-2 infection, and the cumulative incidence of hospital admission, Intensive Care Admission, and death.
NATURE AND EXTENT OF THE BURDEN AND RISKS ASSOCIATED WITH PARTICIPATION, BENEFIT AND GROUP RELATEDNESS: Based on previous experience and randomized controlled trials in adult and elderly individuals, the risks of BCG vaccination are considered low. The objective of this trial is to evaluate the beneficial effects of BCG vaccination through a lower work absenteeism rate of HCW and/or a mitigated clinical course of SARS-CoV-2 infection. The primary endpoint and the adaptive design with frequent interim analyses facilitate maximum efficiency of the trial, so that results can inform policy making during the ongoing epidemic.

### Doel van het onderzoek

BCG vaccination may induce (partial) protection against susceptibility to and/or severity of SARS-CoV-2 infection. This will lead to reduced workplace absenteeism under health care workers taking care of patients with COVID-19

### Onderzoeksopzet

Daily measurements of the primary and secondary endpoints through a mobile application, with two-weekly interim analysis of the primary endpoint starting in week 4 using a Bayesian negative binomial regression model. This means study duration and follow-up is dynamic, with a maximum of 180 days per participant.

**Onderzoeksproduct en/of interventie**

Participants will be randomized between intracutaneous administration of BCG vaccine or placebo in a 1:1 ratio

# Contactpersonen

## Publiek

UMC Utrecht
Thomas van der Vaart

0654245404

## Wetenschappelijk

UMC Utrecht
Thomas van der Vaart

0654245404

# Deelname eisen

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

- Adult (≥18 years);
- Male or female;
- Hospital personnel (expected to) taking care for patients with SARS-CoV-2 infection

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

- Known allergy to (components of) the BCG vaccine or serious adverse events to prior BCG administration;
- Known active or latent Mycobacterium tuberculosis or with another mycobacterial species. A history with- or a suspicion of M. tuberculosis infection;
- Fever (>38 C) within the past 24 hours
- Pregnancy;

- Suspicion of active viral or bacterial infection;
- Vaccination in the past 4 weeks or expected vaccination during the study period, independent of the type of vaccination
- 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 anti-cytokine therapies. i) 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;
- Direct involvement in the design or the execution of the BCG-CORONA study;
- Expected absence from work of ≥4 of the following 12 weeks due to any reason (holidays, maternity leave, retirement, planned surgery etc);
- Employed to the hospital < 22 hours per week;
- Not in possession of a smartphone

# Onderzoeksopzet

## Opzet

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

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 20-03-2020 |
| Aantal proefpersonen: | 1500 |
| 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: | 20-03-2020 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

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

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8477 |
| Ander register | METC Utrecht : 20-139 |

# Resultaten