Enhancing the BCG-induced trained immunity response by addition of bisphosphonate or MMR vaccine: a possible preventive approach against COVID-19 (BCG-PLUS)

Gepubliceerd: 11-05-2020 Laatst bijgewerkt: 18-08-2022

Oral bisphosphonate supplementation or the MMR vaccine can be used as immune potentiators when simultaneously administered with BCG, to further amplify the BCG-induced trained immunity response and maximize potential protective effects against COVID...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27545

Bron
NTR

Verkorte titel
BCG-PLUS

Aandoening

COVID-19, SARS-CoV-2

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: NWO-Spinoza

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the fold-increase in production of pro-inflammatory cytokines by PBMCs/monocytes following vaccination.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: There is currently no specific treatment or vaccine for SARS-CoV-2. Induction of trained immunity by BCG vaccination is a promising non-specific preventive measure, but not all individuals respond equally strongly to it. It is therefore important to maximize the protective potential of BCG. This study will investigate the efficacy of bisphosphonates and the MMR vaccine to enhance trained immunity responses to BCG vaccination.
Objective: To investigate the effect of bisphosphonates and the MMR vaccine on BCG-induced trained immunity.
Study design: Explorative randomized controlled trial.
Study population: Healthy volunteers aged 18-50 years old.
Intervention (if applicable): The intervention groups are as follows:
1. Placebo treatment
2. BCG vaccination
3. BCG vaccination + oral bisphosphonate supplementation (alendronic acid)
4. BCG vaccination + MMR vaccine
5. MMR vaccine alone
Main study parameters/endpoints: The main study parameter is the fold-increase in production of pro-inflammatory cytokines by PBMCs/monocytes following vaccination.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The expected risk of participation is very low. All vaccines and treatments are approved medications and no adverse interactions are expected. BCG can interfere with standard tuberculin skin test for tuberculosis, but an alternative is available (quantiferon). The participants will visit the outpatient clinic twice for blood donations. They will undergo no other invasive procedures for study purposes.

Doel van het onderzoek

Oral bisphosphonate supplementation or the MMR vaccine can be used as immune potentiators when simultaneously administered with BCG, to further amplify the BCG-induced trained immunity response and maximize potential protective effects against COVID-19.

Onderzoeksopzet

0, 28 days

Onderzoeksproduct en/of interventie

1. Placebo treatment
2. BCG vaccination
3. BCG vaccination + oral bisphosphonate supplementation (alendronic acid)
4. BCG vaccination + MMR vaccine
5. MMR vaccine alone

Contactpersonen

Publiek

Radboudumc
Priya Debisarun

0243613889

Wetenschappelijk

Radboudumc
Priya Debisarun

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adult (18-50 years of age);
• Male or female;
• Healthy;
• Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Known allergy to (components of), or any other contraindication to, the BCG vaccine, MMR vaccine, or alendronic acid.
• Known (history of) active or latent Mycobacterium tuberculosis or with another mycobacterial species;
• Prior BCG vaccination;
• Acute illness 2 weeks prior to the study or (suspicion of) active infection;
• Pregnancy;
• Chronic use of any systemic drugs other than oral contraceptives;
• Use of NSAIDs less than 4 weeks prior to start of the study;
• Vaccination in the past 3 months or expected vaccination during the study period, independent of the type of vaccination;
• Medical history associated with immunodeficiency.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	25-05-2020
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8609
Ander register	METC Arnhem-Nijmegen : 2020-6564

Resultaten