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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27545

Source NTR

Brief title BCG-PLUS

Health condition

COVID-19, SARS-CoV-2

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Epigenetic and metabolic changes in monocytes between the aforementioned treatment groups

Study description

Background summary

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.

Study objective

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.

Study design

0, 28 days

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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;

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• 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	25-05-2020
Enrollment:	100
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable Application type:

Not applicable

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
NTR-new	NL8609
Other	METC Arnhem-Nijmegen : 2020-6564

Study results