

Name of the trail: BCG revaccination of health workers to improve innate immune responses against COVID-19 (BCG-COVID19)

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Decision: Include in meta-analysis

Reviewers: AD, KH

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| Patients: | Healthcare workers that have been previously vaccinated with BCG vaccine (nurses, physicians, but also physical therapists and nutritionists with at least 8 hours contact with COVID-19 positive patients) |
| Intervention | BCG vaccination |
| Control: | No vaccination |
| Outcomes: | Incidence of COVID-19, disease severity, mortality |

| Bias | Authors' judgement Low, unclear, high | Support for judgement |
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| Random sequence generation (selection bias) | Low | "randomisation was performed in blocks of 20 participants using the platform randomization.com [http://www.jerrydallal.com/random/permute.htm]" |
| Allocation concealment (selection bias) | Low | "The randomization was prepared before any HW inclusion. The results were printed and inserted in sealed envelopes that were numbered with BCG-001 to BCG-400. The printed results as well the envelopes had the same numbers. At the time of the randomisation, each participant that meets the inclusion criteria will receive a consecutive participant number [BCG-001-BCG-400]. The sealed envelope with the assigned number, blinded to the researchers, will be opened in front of the participant and the arm allocation will be known." |
| Blinding of participants and personnel (performance bias) | High | "There will be no masking for the participants and/or for the caregivers." "An experienced nurse from the Municipal Immunization Program will conduct the immunization." The nurse giving the vaccine will not be blinded but has no role in evaluating the outcomes. |

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| Blinding of outcome assessment (detection bias) | Low | “The study participant’s arms will be blinded to the laboratory researchers and those who will be evaluating the outcomes and performing the statistical analysis” |
| Method of outcome assessment (attrition bias) | Low | Telemonitoring for signs and symptoms of COVID-19 on days 7, 15, 30, 60 and 180 post vaccination. “If any participant presents symptoms, they will be tested for COVID-19 through the rapid chromatography test and will be referred to a referenced network and their samples will be collected for RT-PCR for diagnosis of COVID-19” |
| Other bias | Low | No indications for other bias |