BCG vaccination to minimise COVID-19 disease severity and Duration

(10)(2e) (UMCU), (10)(2e) (Radboud UMC), (10)(2e) (10)(2e) (LUMC), (10)(2e) (10)(2e) (10)(2e) (RIVM)

Samenvatting / Summary
ONDERZOEKSVRAAG
What is the impact of BCG vaccination compared to placebo vaccination on: 1) COVID-19 incidence, severity, and duration; 2)
development and longevity of SARS-CoV-2-specific antibodies and on the immune system more generally; 3) the nasopharyngeal microbiome; and 4) participant-reported upper respiratory tract symptoms that were not due to COVID-19.
URGENTIE
We vaccinated healthcare workers in 9 Dutch hospitals at the start of the first epidemic wave, and plan to follow participants in
3 hospitals (UMCU, Radboud, and LUMC) at 12 and 24 weeks post-vaccination. We require funding to enable laboratory-confirmed outcome assessments now that testing materials and serology tests have become available. If beneficial,
BCG vaccination could be implemented rapidly to protect key populations until SARS-CoV-2-specific vaccines become
available. Because its effects are nonspecific, BCG vaccination could also serve as a first response in future pandemics caused
HYPOTHESE
Our primary hypothesis is that SARS-CoV-2 incidence will be similar in the two arms given the high infectiousness of the virus,
but that disease severity and duration are reduced in the BCG arm.
PLAN VAN AANPAK
Vaccinations have been completed. Participants are reporting clinical data on an ongoing basis via a mobile phone app.
SARS-CoV-2 RT-PCR testing was done at the time of symptom-reporting as part of routine hospital procedures; test results and
stored nasopharyngeal swabs will be retrieved. Serum and saliva specimens will be collected at the 12- and 24-week
post-vaccinations visits, and will be tested for IgG/IgA antibodies against SARS-CoV-2 and against all coronaviruses. The
neutralising capacity of SARS-CoV-2 antibodies will be assessed in a subsample. Nasopharyngeal swabs and blood samples
from participants who were exposed to BCG and SARS-CoV-2, BCG only, SARS-CoV-2 only, or neither will be assessed for
parameters of trained innate immunity and the nasopharyngeal microbiome.
Trefwoorden /