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Effect of BCG vaccination for tuberculosis on COVID-19 in Brazil

Submission date	Recruitment status	[_] Prospectively registered
18/03/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2021	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Bacillus Calmette–Guérin vaccine is a vaccine primarily used against tuberculosis. It is partly named after its inventors Albert Calmette and Camille Guérin. In countries where tuberculosis or leprosy is common, one dose is recommended in healthy babies as close to the time of birth as possible.
This study aimed to estimate and to compare the occurrence and severity of COVID-19 among vaccinated (neonatal BCG vaccination) and revaccinated (neonatal BCG and a second dose of BCG vaccination at school age) in the trial BCGREVAC carried out in 763 state schools located in two Brazilian cities (Salvador and Manaus) during 1996-1998.

Who can participate?
Participants from the BCGREVAC trial (1996 - 1998) who were diagnosed or died from COVID-19 from January 27, 2020, onwards.

What does the study involve?
Records from 200,805 participants from the BCGREVAC trial will be linked with the national database of COVID-19 cases (SIVEP-GRIPE) and the national database of COVID-19 deaths (SIM), from January 27 2020 onwards. We will investigate the association between BCG vaccination status and COVID-19 cases and deaths.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Federal University of Bahia (UFBA) (Brazil)

When is the study starting and how long is it expected to run for?
July 2020 to December 2021

Who is funding the study?
The National Council for Scientific and Technological Development (CNPq) (Brazil)

Who is the main contact?
Dr Susan Martins Pereira, susanmp@gmail.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
401624/2020-0 (CNPq protocol number)

Study information

Scientific Title
Effect of BCG vaccination and revaccination on the occurrence and severity of COVID-19 in Brazil

Acronym
REVAC BCG and COVID-19

Study objectives
To estimate and to compare the occurrence and severity of COVID-19 among vaccinated (neonatal BCG vaccination) and revaccinated (neonatal BCG and a second dose of BCG vaccination at school age) during the trial BCGREVAC.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 03/06/2020, Ethics Committee of the Institute of Collective Health (Federal University of Bahia, Basílio da Gama St., n/n – Canela, Salvador-BA, 40.110-040, Brazil; no telephone number provided; cepisc@ufba.br), ref: CAAE: 32820920.7.1001.5030

Study design
Interventional cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not applicable (retrospective study)

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) in persons who were previously given the BCG vaccine

Interventions
This study looks at patient records from participants in an earlier study who were randomised to receive either vaccination with BCG vaccine produced in Brazil using the Moreaux (Rio de Janeiro) strain, during 1996-1998 or received no vaccination. In each trial arm, vaccination status was evaluated through examination of the BCG scar. This was an open trial, without placebo.

Considering that the randomization performed in the past remains after 22 years of follow-up, the individual records from this trial will be linked with two nationwide health datasets: COVID-19 cases notified in the Brazilian Influenza Surveillance System (SIVEP/Gripe) and the COVID-19 deaths registered in the Brazilian Mortality Information System (SIM) databases, from January 27, 2020, onwards.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bacillus Calmette–Guérin (BCG) vaccine

Primary outcome measure
Measured using patient records at a single timepoint:
1. COVID-19 incidence

2. COVID-19 severity (COVID-19 severity classification: 1) SpO2 < 95% on room air at sea level; 2) vigorous breathing effort; 3) cyanosis; 4) severe pneumonia; 5) Severe Acute Respiratory Syndrome (SARS); 6) sepsis; 7) septic shock)

Secondary outcome measures
Mortality from COVID-19 measured using patient records at a single timepoint

Overall study start date
10/07/2020

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Participants from the BCGREVAC trial (1996 - 1998) who were diagnosed or died from COVID-19 from January 27, 2020, onwards.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
200,805

Total final enrolment
200805

Key exclusion criteria
Does not meet inclusion criteria.

Date of first enrolment
01/06/1996

Date of final enrolment
01/06/1998

Locations

Countries of recruitment
Brazil

Study participating centre
Federal University of Bahia (UFBA)
Institute of Collective Health (ISC)
Salvador
Brazil
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Sponsor information

Organisation
National Council for Scientific and Technological Development

Sponsor details
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Sponsor type
Government

Website
http://www.cnpq.br/

ROR
https://ror.org/03swz6y49

Funder(s)

Funder type
Government

Funder Name
National Council for Scientific and Technological Development (CNPq)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to property rights of the funding agency and ethics reasons related to confidentiality.

IPD sharing plan summary
Stored in repository