Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of BCG Vaccine on Preventing COVID-19 Infection in Healthcare Staff Exposed to SARS-CoV-2

Protocol summary

Study aim

Assessing the effect of the BCG vaccine on preventing COVID-19 infection in healthcare workers exposed to coronavirus

Design

Phase III double blind Placebo-controlled adaptive multi-centre randomized controlled trial. Groups are determined by block randomization to receive a BCG vaccine or normal saline in a 1: 1 ratio.

Settings and conduct

The study will include five hundred healthcare workers in the COVID-19 hospitals in Shiraz, Iran. Participants will be follow-up for 12 months with regular mobile phone text messages to identify COVID-19 infection and related issues.Blood samples will be collected prior to randomization and at 12 months to determine exposure to severe acute respiratory syndrome coronavirus 2.

Participants/Inclusion and exclusion criteria

Inclusion criteria include HCW over 18 years of age, male or female, hospital personnel who take care of patients with SARS CoV-2 infection with a signed and dated informed consent form. Exclusion criteria include HCW with fever, skin infections at the site of vaccine injection, intercurrent respiratory infection, or those who take immunosuppresive medications, those with any serious underlying conditions such as malignancies, receiving any live vaccine, BCG vaccine injection over the past year, having a positive COVID-19 test result.

Intervention groups

Experimental: 0.10 mL intradermal injection of BCG Vaccine over the distal insertion of the deltoid muscle onto the humerus. Placebo Comparator: Placebo intradermal injection of 0.1ml of 0.9% NaCl solution

Main outcome variables

1- Confirmed COVID-19 infection 2- Hospitalization due to COVID-19 3- Death due to COVID-19.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047019N1**
Registration date: **2020-05-18, 1399/02/29**
Registration timing: **prospective**

Last update: **2020-05-18, 1399/02/29**
Update count: **0**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Bahman Pourabbas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4304

Email address

pourabbasb@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-04, 1399/03/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of BCG Vaccine on Preventing COVID-19 Infection in Healthcare Staff Exposed to SARS-CoV-2

Public title
Effect of BCG Vaccine on Preventing COVID-19
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Healthcare workers potentially exposed to patient with COVID-19 infection in hospitals Over 18 years of age Complete the consent form with date and signature Male and female
Exclusion criteria:
Allergy to the BCG vaccine or any BCG vaccine contraindication Fever (>38 C) within the past 24 hours or generalised skin diseases such as infection, eczema, dermatitis or psoriasis at or near the site of vaccination. Pregnancy Cases with active or latent Mycobacterium tuberculosis Known HIV infection Individuals with any serious underlying illness (such as malignancy) except those with cardiovascular disease, hypertension, diabetes, and/or chronic respiratory disease if they are not immunocompromised Live vaccine administered for 4 weeks prior to randomization Suspected to active viral or bacterial infections Individuals with a SARS-CoV-2 positive test result Severely immunocompromised subject or who has taken immunosuppressive therapy in the last years
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **500**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization will be used and the size of the blocks will be selected randomly (for example 8 or 6 participants in each block with an equal number of two groups). In this method, the blocks are determined based on the hospital health care workers information that is in the face of covid 19. In each block, half of the people are considered as intervention groups and the rest half as placebo. The main goal of this method is to balance the number of participants in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Statistical data analyst will distribute the health care workers in randomized blocks using software in two groups including vaccine recipients and placebo. Identical vials without specifications (vials A and B) will be given to nurses for injection. -Participants won't be aware of the injection material. Individuals who won't be aware of the grouping are as follow: -Individuals who receive feedback from participants about influenza-like illness or severe respiratory illness. -People who perform PCR tests to diagnose the coronavirus. -Personnel and researchers who complete information based on questionnaires and register in SPSS software. The final analysis will be performed by the statistical analyst who is informed of the grouping.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz university of medical sciences
Street address
Clinical Microbiology Research center, Nemazi Hospital, Zand St,Zand St.
City
Shiraz
Province
Fars
Postal code
7188858184
Approval date
2020-05-20, 1399/02/31
Ethics committee reference number
IR.SUMS.REC.1399.181

Health conditions studied

1

Description of health condition studied
Coronavirus Disease 2019 (COVID-19)
ICD-10 code
U07.1 COVI
ICD-10 code description
U07.1 COVID-19, virus identified

Primary outcomes

1

Description
COVID-19 infection
Timepoint
Time Frame: At the beginning and weekly for up to 12

months

Method of measurement

A questionare for assessment of fever (>38), cough, shortness of breath, respiratory failure, runny / blocked nose and PCR or serology for detection of SARS-Cov-2

2

Description

Severe COVID-19 disease

Timepoint

Time Frame: At the beginning and weekly for up to 12 months

Method of measurement

A questionare to assess hospitalization or death due to covid-19 infection.

Secondary outcomes

1

Description

Hospital admission duration due to SARS-CoV-2

Timepoint

At the beginning and weekly for up to 12 months

Method of measurement

Review of hospital records

2

Description

Hospital admission due to documented SARS-CoV-2 infection

Timepoint

Review of hospital records

Method of measurement

Incidnce of hospitalization days due to documented SARS-CoV-2 infection

3

Description

Pneumonia

Timepoint

At the beginning and weekly for up to 12 months

Method of measurement

Number of pneumonia cases with abnormal chest X-rays or CT scan and evaluation the extent of lung involvement

4

Description

Mechanical ventilation duration with SARS-CoV-2

Timepoint

At the beginning and weekly for up to 12 months

Method of measurement

Review of hospital records

5

Description

ICU admission duration due to SARS-CoV-2

Timepoint

At the beginning and weekly for up to 12 months

Method of measurement

Review of hospital records

6

Description

Mechanical ventilation usage in patients with SARS-CoV-2

Timepoint

At the beginning and weekly for up to 12 months

Method of measurement

Review of hospital records

7

Description

Number of days absence at work due to febrile respiratory illness

Timepoint

At the beginning and weekly for up to 12 months

Method of measurement

self-reporting

8

Description

Seroconversion of SARS-CoV-2-specific antibodies (IgM,G)

Timepoint

At the beginning, during the study (if symptoms occurs) and at 12 months

Method of measurement

Measurement of plasma/serum SARS-CoV-2-specific antibodies (IgM,G) at vaccination time and also the end of the study period.

9

Description

Intensive care unit admission due to documented SARS-CoV-2 infection

Timepoint

At the beginning and weekly for up to 12 months

Method of measurement

Review of hospital records

Intervention groups

1

Description

Intervention group: Healthcare workers who are exposed to the pandemic virus (COVID-19) will be randomly assigned to receive 0.1 ml intradermal injection of BCG vaccine. All participants will be followed-up for 12 months by text messages (up to weekly). The Mantoux Tuberculin skin test (before receiving the BCG vaccine) will be performed by intradermal injection of 0.1 ml (PPD) in front of the left forearm. This test will be read after 48-72 hours, a positive tuberculin test is 10 mm or more. Blood samples will be collected at the beginning and 12 months for PCR and antibody detection.

Category
Prevention

2

Description
Control group: Healthcare workers who are exposed to the pandemic virus (COVID-19) will be randomly assigned to receive 0.1 ml intradermal injection of BCG vaccine. All participants will be followed-up for 12 months by text messages (up to weekly). The Mantoux Tuberculin skin test (before receiving the BCG vaccine) will be performed by intradermal injection of 0.1 ml (PPD) in front of the left forearm. This test will be read after 48-72 hours, a positive tuberculin test is 10 mm or more. Blood samples will be collected at the beginning and 12 months for PCR and antibody detection.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali asghar hospital
Full name of responsible person
Ali Akbari
Street address
Meshkinfam St.
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Fars
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Phone
+98 71 3228 8602
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+98 71 3228 8907
Email
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2

Recruitment center
Name of recruitment center
Faghihi hospital
Full name of responsible person
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7134844119
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3

Recruitment center
Name of recruitment center
Rajaee hospital
Full name of responsible person
Ali Akbari
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4

Recruitment center
Name of recruitment center
Nemazi hospital
Full name of responsible person
Mohsen Moghadami
Street address
Zand st.
City
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Postal code
7193613311
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Email
nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Professor Alborzi Clinical Microbiology Research Center, Shiraz University of Mdical Sciences
Full name of responsible person
GHolamreza Pouladfar
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Nemazi hospital. Zand streat
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Province
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Phone

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Email

alborzicmrc@sums.ac.ir

Grant name

covid-19 grant

Grant code / Reference number

99-01-106-22342

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

25

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Bahman Pourabbas

Position

Assisstant professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

Street address

Prof. Alborzi Clinical Microbiology Research Center - Nemazi Hospital- Zand St.- Ŝhiraz - Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Pouladfar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Bahman Pourabbas

Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected deidentified IPD will be shared.

When the data will become available and for how long

The data will become available starting 6 months after publication for 1 year.

To whom data/document is available

It will be available for people working in academic institutions.

Under which criteria data/document could be used

The data will be shared by request and the persons who are responsible for general and scientific inequires will review the request.

From where data/document is obtainable

person who are responsible for general inequires: Bahman Pourabbas bpourabbas@yahoo.com person who are responsible for scientific inequires: Gholamreza Pouladfar pouladfar_ghr@hotmail.com

What processes are involved for a request to access data/document

The academic applicants should send their request by email. The responsible persons will answer up to 2 weeks.

Comments