

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Feb 2026

A Clinical trial to evaluate the immunogenicity and safety of Omicron-Based CovIran Barkat vaccine as a third injection dose in vaccinated population over 18 years of age

Protocol summary

Study aim

To evaluate the immunogenicity and safety of Omicron-Based CovIran Barkat vaccine as a third injection dose in vaccinated population over 18 years of age

Design

Non-randomized clinical trial with a parallel design on 210 volunteers over the age of 18 with a history of two-dose vaccination with an inactivated vaccine

Settings and conduct

This Non-randomized clinical trial study will be conducted on 210 volunteers aged ≥ 18 years at Eram Hotel and Eshragh vaccination centre. They will be followed up for safety, immunogenicity, any adverse events, and COVID-19 incidence.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: Aged over 18 years old, In the volunteer's vaccination history, the interval between the first and second dose is 4 to 8 weeks and at least 3 months and at most 5 months have passed since the injection of the 2nd dose of the volunteer vaccine, willing to participate, able to understand, sign the informed consent, medically stable condition for the past 3 months/ Main exclusion criteria: Confirmed, suspected, or asymptomatic COVID-19, History of SARS-CoV-2 (documented rtPCR) after the second dose, any abnormal paraclinical findings, history of allergy to the vaccine, any neurologic disease, immunodeficiency, coagulopathy, psychiatric and other chronic diseases, receiving the live vaccine in 14 days before inoculation, receiving immunoglobulins or blood products in 3 months before inoculation, women with a positive Beta HCG or breastfeeding or pregnancy intention.

Intervention groups

1. 3rd injection of CovIran Barkat of Wuhan strain 2. 3rd injection of CovIran Barkat of Omicron strain, both with a history of receiving two doses of CovIran Barkat 3. 3rd injection of COVIran Barekat of Omicron strain, with a

history of receiving two doses of Sinopharm

Main outcome variables

Humoral immunity (Seroconversion, Neutralizing Ab, Anti-RBD, Anti-SPIKE)

General information

Reason for update

Amendments in data sharing section

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037571N4**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-15, 1402/08/24**

Update count: **2**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Hamed Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

hmdhosseini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-26, 1400/12/07

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to evaluate the immunogenicity and safety of Omicron-Based CovIran Barkat vaccine as a third injection dose in vaccinated population over 18 years of age

Public title

A Clinical trial of Omicron-Based CovIran Barkat vaccine as a third injection dose in vaccinated population over 18 years of age

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged over 18 years old In the volunteer's vaccination history, the interval between the first and second dose is between 4 to 8 weeks and at least 3 months and at most 5 months have passed since the injection of the second dose of the volunteer's vaccination. The volunteer must be able and willing to cooperate with the researchers throughout the study period. The volunteer must be able to fully understand the executive processes of the study and to understand the explanations of the facilitators correctly. The volunteer would be able to understand the contents of the informed consent form and sign the informed consent before recruitment. Access to the medical records and test results if hospitalised for any reason including due to the suspected or confirmed COVID-19 should be allowed. The volunteer has been in a medically stable condition for the past three months (he/she has not been hospitalized, his / her chronic illness has not recurred). His / her chronic illness medication instructions have not changed due to lack of control over clinical symptoms, etc.)

Exclusion criteria:

Confirmed, suspected, or asymptomatic COVID-19 case Candidate with a history of SARS-CoV-2 infection (documented rtPCR) after receiving the second dose of COVID-19 vaccine. During the period of home quarantine due to Covid-19 (suspicion of exposure or suspicious symptoms). In the 14 days prior to vaccination: fever or presence of at least two symptoms from Dry cough, severe fatigue, nasal congestion, runny nose, sore throat, myalgia, diarrhoea, dyspnea, and shortness of breath History of severe allergic reaction, urticaria or allergic reactions to COVID-19 Inactivated vaccine ingredients (allergic to Aluminium). Personal or family history of seizure, epilepsy, encephalopathy or psychiatric disorders Presence of congenital malformations or any genetic disorder Presence of any malignancy Known case of immunodeficiency, HIV, lymphoma, leukemia, or other autoimmune diseases. Receiving immunosuppressive drugs or corticosteroids in the last 6 months Splenectomy or history of any organ removal History of coagulation disorders History of hereditary and acquired angioedema over the past year

Receiving Anti-TB treatment Positive HBsAg/ Positive HCV antibody Receiving immunomodulators or immunosuppressors at least for 14 days in the past 3 months Receiving live vaccine in one month or other vaccines in 14 days before inoculation Receiving immunoglobulins or blood products in 3 months before inoculation History of severe mental disorders affecting the participation in the study Women with a positive pregnancy test (Beta HCG in a blood sample) or breastfeeding or those who intend to become pregnant during the study period. Any other circumstances are other than the above-mentioned ones that the researcher deems inappropriate for a person participating in a clinical trial. These cases are recorded as the reason for not entering.

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **210****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National research ethics committee

Street address

13th floor, Block A, Ministry of health, Simaye Iran street, Shahrake ghods(qarb)

City

Tehran

Province

Tehran

Postal code

1417993337

Approval date

2022-02-22, 1400/12/03

Ethics committee reference number

IR.NREC.1400.021

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Total IgG titers against Wuhan and Omicron variants (with GMT, GMI)

Timepoint

Days 0,14, 90, 180

Method of measurement

ELISA assay

2

Description

The neutralization capacity of booster doses against Wuhan and Omicron variants

Timepoint

Days 0,14, 90, 180

Method of measurement

Conventional Virus Neutralization Test (cVNT)

Secondary outcomes

1

Description

Any immediate reaction after inoculation

Timepoint

0-30 minutes after inoculation

Method of measurement

Close observation

2

Description

Percentage of local reactions (pain, redness, swelling,in injection site)

Timepoint

Days 0 to 7 after each inoculation

Method of measurement

Examination, history, and report of the study participant based on the Vaccine Adverse Event Reporting System

3

Description

Percentage of systemic events (fever, headache, chills, nausea, vomiting, diarrhoea, fatigue, muscle pain, arthralgia,)

Timepoint

Days 0 to 7 after inoculation

Method of measurement

Examination, history, and report of the study participant based on the Vaccine Adverse Event Reporting System

4

Description

Occurrence of any adverse event (serious or non-serious)

Timepoint

Days 0 to 7 after inoculation

Method of measurement

Examination, history, and report of the study participant based on the Vaccine Adverse Event Reporting System

5

Description

Occurrence of any systemic events

Timepoint

Days 0 to 180 after inoculation

Method of measurement

Examination, history, and report of the study participant based on the Vaccine Adverse Event Reporting System

6

Description

Occurrence of any adverse event (serious or non-serious)

Timepoint

Days 0 to 180 after inoculation

Method of measurement

Examination, history, and report of the study participant based on the Vaccine Adverse Event Reporting System

7

Description

Occurrence and the severity of SARS-COV-2 infection

Timepoint

Till 180 days after inoculation

Method of measurement

Comparing confirmed COVID-19 cases, severity status is categorised as non-severe, severe, and critical based on the WHO diagnosis scheme.

Intervention groups

1

Description

Group of recipients of the third injection of CovIran Barkat vaccine of Wuhan strain, with a history of receiving two doses of CovIran Barkat vaccine

Category

Prevention

2

Description

Group of recipients of the third injection of CovIran Barkat vaccine of Omicron strain, with a history of receiving two doses of CovIran Barkat vaccine

Category

Prevention

3**Description**

Group of recipients of the third injection of Covlran Barkat vaccine of Omicron strain, with a history of receiving two doses of Sinopharm vaccine

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Eram Grand Hotel

Full name of responsible person

Minoo Mohraz, Mohamadreza Salehi

Street address

Near West Hemmat Highway, Haghani Highway,
Vanak square

City

Tehran

Province

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Postal code

1417993337

Phone

+98 21 2226 6644

Email

lkafami@gmail.com

Web page address<https://tehraneramhotel.com/>**2****Recruitment center****Name of recruitment center**

Eshragh vaccination centre

Full name of responsible person

Minoo Mohraz, Mohamadreza Salehi

Street address

Jashnvareh Street, in front of Farhangsara subway
station

City

Tehran

Province

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1657613789

Phone

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Email

preshragh@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

SHIFAPHARMED Industrial Group Co

Full name of responsible person

Hasan Jalili

Street address

Soha St., Shifa St., Mapna Blv

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Kordan

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Alborz

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1417993337

Phone

+98 21 9109 0245

Email

hjalili@ut.ac.ir

Web page address<http://www.shifapharmed.com/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

SHIFAPHARMED Industrial Group Co

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Industry

Person responsible for general inquiries**Contact****Name of organization / entity**

SHIFAPHARMED Industrial Group Co

Full name of responsible person

Hasan Jalili

Position

Managing Director

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Minooh Mohraz

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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AIDS research center, Tehran University of Medical Sciences

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Province

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hamed Hosseini

Position

Epidemiologist

Latest degree

Ph.D.

Other areas of specialty/work

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Street address

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Web page address

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

De-identified, individual participant data will be made available upon requests directed to the corresponding author; after the approval of a proposal, data can be shared through a secure online platform.

When the data will become available and for how long

Access will be granted after publishing the results

To whom data/document is available

Anyone who requests

Under which criteria data/document could be used

Categorization and reanalysis of data is permitted. The publication of analysis results is possible only with the permission of the corresponding author of the article.

From where data/document is obtainable

Requests directed to the corresponding author

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

Request from the corresponding author, granting access to anonymized data in one month

Comments