Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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 for14 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.
Age
From **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 CovIran 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
Tehran
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
Tehran
Postal code
1657613789
Phone
+98 21 7732 4113
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
City
Kordan
Province
Alborz
Postal code
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
Street address
Soha St., Shifa St., Mapna Blv
City
kordan
Province
Alborz
Postal code
1417993337
Phone
+98 21 9109 0245

Email
hjalili@ut.ac.ir
Web page address
http://www.shifapharmed.com/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Minoo Mohraz
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
AIDS research center, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417993337
Phone
+98 21 6658 1583
Email
minoomohraz@gmail.com
Web page address
https://ircha.tums.ac.ir/

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
Epidemiology
Street address
Unit 23, 4th floor, No. 1547, North Kargar Street
City
Tehran
Province
Tehran
Postal code
1417993337
Phone
+98 21 8896 3546
Email
hmdhosseini@gmail.com
Web page address
http://ctc.tums.ac.ir

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