

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of safety and immunogenicity of FAKHRAVAC and Sinopharm booster doses for adults 18 years of age and older, fully vaccinated by Sinopharm: a parallel 2 arms, randomised, double blind clinical trial

Protocol summary

Study aim

Comparison of safety and immunogenicity of FAKHRAVAC and Sinopharm booster dose for adults 18 years of age and older, fully vaccinated by Sinopharm

Design

Randomized, double blind, controlled trial with parallel group design on 400 volunteers in 2 groups of 200, stratified on for time periods since the last dose of primary vaccination (75-105, 106-135, 136-165, 166-195 days).

Settings and conduct

SASAD Sports Complex, Shahid Fakhrizadeh Street, Sayad Shirazi Highway

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age more than 18 years; Not having COVID 19 since the last dose of primary vaccination with Sinopharm; Fully vaccinated and within the 75 to 195 days post vaccination period; Signing the informed consent form. Main exclusion criteria: Current acute or chronic symptomatic illness that requires ongoing medical or surgical care; History of severe cardiovascular disease; Pregnancy and lactation.

Intervention groups

Intervention group1: One dose of FAKHRAVAC vaccine injected in the deltoid muscle (IM) Intervention group2: One dose of Sinopharm vaccine injected in the deltoid muscle (IM)

Main outcome variables

Primary outcome: Neutralizing antibody activity 2 weeks after the booster dose Secondary outcomes: Abnormal vital signs and anaphylactic reactions immediately after vaccination; Local and systemic reactions within the first week after booster dose; Serum ELISA IgG level for SARS-CoV-2 N, S1-RBD antigens; SAEs, SUSARs, MAAEs, up to a month following the booster dose; Neutralizing antibody activity and serum ELISA IgG level for SARS-CoV-2 N, S1-RBD antigens, 3 and 6 months after the booster dose (in

a subgroup of participants).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210206050259N4**

Registration date: **2021-11-29, 1400/09/08**

Registration timing: **prospective**

Last update: **2021-11-29, 1400/09/08**

Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name

Ahmad Karimi Rahjerdi

Name of organization / entity

Stem Cell Technology Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of safety and immunogenicity of FAKHRAVAC and Sinopharm booster doses for adults 18 years of age and older, fully vaccinated by Sinopharm: a parallel 2 arms, randomised, double blind clinical trial

Public title
Comparison of safety and immunogenicity of FAKHRAVAC and Sinopharm booster doses for adults 18 years of age and older, fully vaccinated by Sinopharm

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age more than 18; Not having COVID 19 since the last dose of primary vaccination with Sinopharm; Fully vaccinated and within the 75 to 195 days post vaccination period; Signing the informed consent form; For females of childbearing age 18 to 49 years: use of at least one effective method of contraception (condom, oral contraceptive pills, intrauterine device, norplant capsule) and willing to continue up to two month after the booster dose.
Exclusion criteria:
 History of allergy to drugs or vaccines (e.g urticaria and fever); Current acute or chronic symptomatic illness that requires ongoing medical or surgical care; History of severe cardiovascular disease; Lactation; History of receiving any vaccine during the 14 days period prior to the day of receiving booster dose; History of transfusion of any blood product or immunoglobulin within the 3 months period before receiving booster dose; History of diseases resulting in immunosuppression (suspected and definite); History of long-term use of immunosuppressive drugs or systemic corticosteroids in the last 4 months period leading up to the screening day; History of diagnosis or treatment for cancer (except basal cell carcinoma and Insitu cervical cancer); History of uncontrolled serious psychiatric illnesses; History of blood disorders (Blood Dyscrasias, coagulation disorders, platelet deficiency, etc); History of chronic neurological diseases (including seizure and epilepsy); Current drug/alcohol abuse (addiction); Acute febrile illness at the time of booster vaccine injection; Having splenectomy for any reason; Any close contact with a definitively infected person with COVID-19 within the two weeks period before the day of receiving the booster dose; Current use of anticoagulants such as coumarin and related anticoagulants (such as warfarin) or new oral anticoagulants / antiplatelet agents. Note: Less than 325 mg of aspirin per day as prophylaxis is allowed; Chronic unstable disease (last 4 weeks) at the discretion of the principal investigator; Pregnancy.

Age
From **18 years** old

Gender
Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **400**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, stratified block randomization method with block size of 4 was used to assign each participant to the intervention groups. The rand() function of Excel software were used to generate random sequence within each block. After determining the allocated intervention, a non-repetitive five-digit random code was assigned to each participant.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the control group will receive the Sinopharm vaccine, which has different packaging and shape compared to FakhraVac. Therefore, implementation of blinding will be done by a person who will be responsible for this. This is the only person who will not be blind to the intervention given. Once the participant becomes eligible to receive the vaccine, a concealment/randomization code will be assigned to the volunteer and the vaccine type will be displayed on the screen of the vaccinator until the inoculation is confirmed.

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
 Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town, Tehran, Iran
City
 Tehran
Province
 Tehran
Postal code
 7334144696
Approval date

Health conditions studied

1

Description of health condition studied

Respiratory Distress Syndrome due to SARS-CoV-2

ICD-10 code

U07.1

ICD-10 code description

ICD-10COVID-19, virus identified

Primary outcomes

1

Description

Neutralizing antibody activity

Timepoint

On day zero, two weeks, 3 and 6 months after the booster dose injection

Method of measurement

SARS-CoV-2 virus neutralizing antibody titer measured in bio-safety level III lab using conventional method.

Secondary outcomes

1

Description

Abnormal vital signs and anaphylactic reactions immediately after vaccination

Timepoint

In the first half an hour after the booster dose

Method of measurement

Temperature is measured using a digital thermometer. Respiratory rate will be counted by the research staff over one minute. Blood pressure and heart rate will be measured by a digital sphygmomanometer in a sitting position.

2

Description

Local adverse reactions within the first week after booster dose

Timepoint

Daily, within the first week after the booster dose

Method of measurement

Via mobile application, study staff will contact participants who fail to fill their application and complete a local adverse reaction form on their behalf.

3

Description

Systemic adverse reactions within the first week after booster dose

Timepoint

Daily, within the first week after booster dose

Method of measurement

Via mobile application, study staff will contact participants who fail to fill their application and complete a systemic adverse reaction form on their behalf.

4

Description

SAEs, SUSARs, MAAEs, up to 1 month after the booster dose

Timepoint

Up to one month after the booster dose

Method of measurement

Via mobile application. There will be a 24-7 followup center with physicians available all the time.

5

Description

Serum ELISA IgG level for SARS-CoV-2 N, S1-RBD antigens

Timepoint

On day zero, two weeks, 3 and 6 months after the booster dose vaccine

Method of measurement

ELISA method

Intervention groups

1

Description

Intervention group1: One dose of FAKHRAVAC vaccine injected in the deltoid muscle (IM) Intervention

Category

Prevention

2

Description

Intervention group2: One dose of Sinopharm vaccine injected in the deltoid muscle (IM)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fakhra clinical trial center

Full name of responsible person

Mohsen Forughizadeh Moghadam

Street address

Fakhra clinical trial center, Persian Gulf Hall, SASAD Sports Complex, Shahid Fakhrizadeh Street, Sayad Shirazi Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Organization of Defensive Innovation and Research
Full name of responsible person
Ahmad Karimi Rahjerdi
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Grant name

Grant code / Reference number

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

No

Title of funding source

Organization of Defensive Innovation and Research

Proportion provided by this source

100

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Malek Ashtar University
Full name of responsible person
Mohsen ForoughiZadeh Moghadam
Position
Assistant professor
Latest degree
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

Name of organization / entity
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Email

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Deidentified IPD on study outcomes could be shared.

When the data will become available and for how long

After completion of the study and publication of the results, data could be shared for 2 years

To whom data/document is available

Data is available only to members of academic institutions within joint projects with MILAD Daru Nour Co

Under which criteria data/document could be used

Proposal should be presented to MILAD Daru Nour Co. A scientific Advisory committee to MILAD Daru Nour Co should confirm necessity and scientific validity of the proposed joint project

From where data/document is obtainable

You can contact Ms Kousar Naderi at k.naderi@strc.ac.ir

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

Request for data will be made available within the approved joint projects

Comments