# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Nov 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**

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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 than18; 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 Zarafashan & South Falamak, Qods Town, Tehran, Iran

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Tehran

**Province**

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**Postal code**

7334144696

**Approval date**

2021-11-28, 1400/09/07

**Ethics committee reference number**

IR.NREC.1400.014

## 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 titter 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

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## Sponsors / Funding sources

**1**

**Sponsor**
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Organization of Defensive Innovation and Research
**Full name of responsible person**
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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
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## Person responsible for scientific inquiries

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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**