Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Dec 2021

Comparison of the safety, efficacy and immunogenicity of Fakhravac and Sinopharm SARS-CoV-2 vaccines, in adults aged 18 and over; a phase III randomised, non-inferiority clinical trial

Protocol summary

Study aim

Comparison of the safety, immunogenicity and efficacy of Fakhravac and Sinopharm SARS-CoV-2 vaccines

Design

Randomized, double blind, controlled trial with parallel design on 41128 volunteers in 2 groups of 20564, double blind and randomized, using non-inferiority design.

Settings and conduct

1-SASAD Sports Complex, Shahid Fakhrizadeh Street, Sayad Shirazi Highway; 2-Mobile center

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age>18; Internet and smart mobile phone access; No current COVID-19 disease; No pregnancy; Signing the informed consent form; Exclusion criteria: Current acute or chronic symptomatic illness; Acute febrile illness; Lactation; Receiving COVID19 vaccine; Transfusion of any blood product or immunoglobulin; Long-term use of immunosuppressive drugs or systemic corticosteroids; Having cancer; Uncontrol serious psychiatric illnesses; Blood disorders; Continued use of anticoagulants; Current drug or alcohol abuse; Close contact with a person having confirmed COVID-19

Intervention groups

Intervention group: Two doses of Fakhravac vaccine in 3 wks interval; Control group: Two doses of Sinopharm vaccine

Main outcome variables

Primary: Occurrence of confirmed Covid-19 disease two weeks after second dose; Secondary: Occurrence of confirmed moderate or severe cases or death due to Covid-19 two weeks after the second dose; Occurrence of confirmed severe cases or death due to Covid-19 two weeks after the second dose; Abnormal vital signs and anaphylactic reactions immediately after vaccination; Local adverse events within the first week post-vaccination; Systemic adverse event within the first week post-vaccination; Serious Adverse Event/Reaction, Suspected Unexpected Serious Adverse Reaction, Medically Attended Adverse Events; Serum IgG level for SARS-CoV-2 to N, and S1-RBD antigens (subgroup of 200); Neutralizing antibody titers (subgroup of 200)

General information

Reason for update

Addition of mobile centers; Addition of two non-random arms; Change in inclusion and exclusion criteria

Acronym

IRCT registration information

IRCT registration number: **IRCT20210206050259N3**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **prospective**

Last update: **2021-10-11, 1400/07/19**
Update count: **1**

Registration date

2021-08-29, 1400/06/07

Registrant information

Name

Ahmad Karimi Rahjerdi

Name of organization / entity

Stem Cell Technology Research Center

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the safety, efficacy and immunogenicity of Fakhravac and Sinopharm SARS-CoV-2 vaccines, in adults aged 18 and over; a phase III randomised, non-inferiority clinical trial

Public title

Comparison of the safety and efficacy of Fakhravac and Sinopharm SARS-CoV-2 vaccines, in adults aged 18 and over

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age > 18; Having Iranian citizenship; Internet and smart mobile access (him/herself or one of him/his family); Living in and around the city where the trial takes place; No current COVID-19 disease; No pregnancy; Using safe methods of contraception; Signing the informed consent form.

Exclusion criteria:

Current acute or chronic symptomatic illness that requires ongoing medical or surgical care; Acute febrile illness; Lactation; History of receiving COVID19 vaccine; History of transfusion of any blood product or immunoglobulin within the 3 months before the study; History of long-term use (14 successive days) of immunosuppressive drugs or systemic corticosteroids in the last 4 months leading up to the study; History of diagnosis or treatment for HIV; History of allergic diseases such as angioedema or anaphylactic reactions following the use of drugs, vaccines or food; 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); Continued 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.; Current drug or alcohol abuse (addiction); Close contact with a definite case of COVID-19 up to two weeks prior to the day of receiving the first dose; Chronic diseases that are not listed as exclusion criteria but are considered unstable within the last 4 weeks.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **41128**

Randomization (investigator's opinion)

Randomized

Randomization description

This study uses both randomized and non-randomized arms. Block randomization method with variable block sizes of 4 and 6 in STATA will be used to create the random sequence in randomized arms. For the purpose of concealment, a unique code will be assigned to each intervention the participants receive, and all subjects will be identified with this code until the end of the study (concealment code).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the control group will receive the Sinopharm vaccine, which has different packaging (volume 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. Non-randomized arms that were added to the study later on, are not blind.

Placebo

Not used

Assignment

Parallel

Other design features

In addition to the randomized arms, two non-randomised and open label arms were added to the study. Participants will receive one of the FAKHRAVAC or Sinofarm vaccines by their own choice in these additional arms.

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

City

Tehran

Province
Tehran
Postal code
7334144696
Approval date
2021-08-24, 1400/06/02
Ethics committee reference number
IR.NREC.1400.006

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
COVID-19, virus identified

Primary outcomes

1

Description
Occurrence of confirmed symptomatic Covid-19 disease two weeks after the second vaccine dose
Timepoint
Two weeks after the second dose of the vaccine up to 6 months
Method of measurement
Clinical assessments and PCR test

Secondary outcomes

1

Description
Occurrence of confirmed moderate, or severe illness or death due to Covid-19 infection two weeks after the second vaccine dose
Timepoint
Two weeks after the second vaccine dose up to 6 months
Method of measurement
Clinical assessments and PCR test

2

Description
Occurrence of confirmed severe cases or death due to Covid-19 infection two weeks after the second vaccine dose
Timepoint
Two weeks after the second vaccine dose up to 6 months
Method of measurement
Clinical assessments and PCR test

3

Description
Abnormal vital signs and anaphylactic reactions immediately after vaccination
Timepoint
In the first half an hour after each vaccine 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.

4

Description
Local adverse events within the first week post-vaccination
Timepoint
For the first 6 days after each vaccine dose
Method of measurement
Record daily symptoms using a mobile phone application

5

Description
Systemic adverse event within the first week post-vaccination
Timepoint
For the first 6 days after each vaccine dose
Method of measurement
Record daily symptoms using a mobile phone application

6

Description
Serious Adverse Event/Reaction(SAEs) , Suspected Unexpected Serious Adverse Reaction (SUSARs), Medically Attended Adverse Events (MAAEs)
Timepoint
Up to six months after the last dose of the vaccine
Method of measurement
adverse events will be assessed monthly up to 6 months

7

Description
Serum IgG level for SARS-CoV-2 N, S1-RBD antigens
Timepoint
on days zero, second injection day, day 42 and at 3, 6 months after the first vaccination.
Method of measurement
ELISA method

8

Description
Neutralizing antibody activity
Timepoint
on days zero, second injection day, day 42 and at 3, 6 months after the first vaccination.
Method of measurement
SARS-CoV-2 virus neutralizing antibody titer measured using a biosafety level III

Intervention groups

1

Description
Intervention group: Two doses of 10 micro gram vaccine injected in the deltoid muscle (IM) at 21 days interval
Category
Prevention

2

Description
Control group: Two doses of Sinopharm vaccine injected in the deltoid muscle (IM) at 21 days interval
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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Province
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Postal code
1986936911
Phone
+98 21 2610 1694
Email
Foroughizadeh@modares.ac.ir
Web page address
http://www.fakhravac.ir

2

Recruitment center
Name of recruitment center
Mobile center
Full name of responsible person
Pouria Basiri
Street address
Area of Tehran and Karaj
City
Tehran
Province
Tehran
Postal code
1986936911
Phone
+98 21 2610 1694
Email
pouriabasiry@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Organization of Defensive Innovation and Research
Full name of responsible person
Ahmad Karimi Rahjerdi
Street address
NO.9, Unit 3, Mirsharifi, Valiasr St.
City
Tehran
Province
Tehran
Postal code
1986936911
Phone
+98 21 2265 8405
Email
Rahjerdi@strc.ac.ir
Web page address
http://miladpharmaceuticsco.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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 ForughiZadeh Moghadam
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Genetics
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Malek Ashtar University, Shabanloo St., Lavizan
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Phone
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Ramin Hamidi Farahani
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Associate professor
Latest degree
Specialist
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Infectious diseases
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Person responsible for updating data

Contact
Name of organization / entity
Milad Daro Noor Pharmaceutical Co.
Full name of responsible person
Kosar Naderi
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Assistant Professor
Latest degree
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Other areas of specialty/work
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Tehran
Postal code
1986936911
Phone
+98 21 2265 8405
Email
k.naderi@strc.ac.ir

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