Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Phase 2 trial of safety and immunogenicity of 10 micro gram inactivated SARS-CoV-2 vaccine (FAKHRAVAC), two doses two weeks apart in adults aged 18-70 years: a randomized, double-blind, placebo-controlled, clinical trial

Protocol summary

Study aim
Safety and immunogenicity of Covid 19 FAKHRAVAC (MIVAC) inactivated vaccine in healthy population 18-70 years

Design
Randomized, double blind, controlled trial with parallel design on 500 volunteers in 2 groups of 250, double blind and randomized.

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

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18-70 years; BMI 18-35; No current or previous COVID-19 infection; Use of safe methods of contraception; Signing informed consent. Exclusion criteria: Current acute or chronic illness requiring regular medical or surgical attention; High-risk occupations exposed to Covid-19; serving in obligatory military service; Breastfeeding; Pregnancy.

Intervention groups
Group 1: vaccine strength of 10 micro gram, two doses at 14-day intervals Group 2: Receiving two doses placebo at 14-day intervals

Main outcome variables
Primary outcomes: Reactogenicity (vital signs and anaphylactic reactions 3 hours post-vaccination; Local and systemic adverse events within the first week post-vaccination; Serum IgG level for SARS-CoV-2 to N, S1-RBD antigens up to a year. Secondary outcomes: Abnormal laboratory findings one week after vaccine injection; SAEs, SUSARs, MAAEs up to six months after the last dose of the vaccine; Occurrence of Covid-19 disease two weeks after the second dose of the vaccine onwards; Neutralizing antibody activity; Cell medicated immunity and safety of cell-mediated immune response.

General information

Reason for update
Recording of the actual start and end recruitment date and increase in the number of humoral immunity test occasions

Acronym

IRCT registration information
IRCT registration number: **IRCT20210206050259N2**
Registration date: **2021-06-08, 1400/03/18**
Registration timing: **prospective**

Last update: **2022-07-02, 1401/04/11**
Update count: **3**

Registration date
2021-06-08, 1400/03/18

Registrant information

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Name of organization / entity
Stem Cell Technology Research Center

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-09, 1400/03/19

Expected recruitment end date
2021-07-06, 1400/04/15

Actual recruitment start date

2021-06-09, 1400/03/19

Actual recruitment end date

2021-07-06, 1400/04/15

Trial completion date

2022-01-16, 1400/10/26

Scientific title

Phase 2 trial of safety and immunogenicity of 10 micro gram inactivated SARS-CoV-2 vaccine (FAKHRAVAC), two doses two weeks apart in adults aged 18-70 years: a randomized, double-blind, placebo-controlled, clinical trial

Public title

Trial of safety and immunogenicity of 10 micro gram inactivated SARS-CoV-2 vaccine FAKHRAVAC (MIVAC)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 70 years Body mass index between 18 and 35 kg per square meter No current or previous COVID-19 disease No pregnancy Using safe methods of contraception Signing the informed consent form Having Iranian citizenship Participants should be able to read and understand informed consent, preferably having an education at a diploma or higher level. Temperatures less than or equal to 37.2 ° C, sublingual, measured by a digital thermometer Negative IgG and IgM antibody titers against COVID-19 N antigen Negative RT-PCR -test for SARS-CoV-2 IgG ELISA negative blood test against HIV Heart rate between 60 and 100 Systolic blood pressure (between 90 and 140 mm Hg), Diastolic blood pressure (between 60 and 90 mm Hg) Committing to observing the requested behavioral protocol to reduce the risk of COVID-19 Negative pregnancy test for β-hCG on the day of screening and the day of vaccination Clinical trial participants should refrain from donating blood or plasma from the first vaccination until three months after the last vaccination. Participants should not enter any other trial while in this study Expressing readiness to remain in the study for the entire study period Use one of a safe methods of contraception in men and women up to 3 months after the last dose of the vaccine

Exclusion criteria:

Current acute or chronic symptomatic illness that requires ongoing medical or surgical care High-risk occupations regarding the risk of acquiring COVID-19, including medical staff, occupations with close contact with many clients Serving in compulsory military service (soldiers) in the subdivisions of the Armed Forces Breastfeeding History of receiving any research vaccine during the 30 days before the day of screening History of transfusion of any blood product or immunoglobulin within the three months before the screening day History of long-term use of immunosuppressive drugs or systemic corticosteroids in the last four months leading up to screening day History of allergic diseases such as angioedema or anaphylactic reactions History of any allergy to drugs or vaccines History of cancer or chemotherapy in the last 5 years History of serious psychiatric illnesses History of blood disorders (Blood Dyscrasias, coagulation, platelet deficiency or disorder, etc) Having chronic obstructive pulmonary disease such as asthma and COPD, ischemic cardiovascular disease diagnosed and treated by a specialist Uncontrolled blood pressure (systolic higher than 140 and diastolic higher than 90) Uncontrolled diabetes (HbA1c higher than six or BS higher than 140) or diabetes treatment by insulin History of chronic neurological diseases (including seizures and epilepsy) Having thyroid disease or a history of thyroidectomy except for controlled hypothyroidism Any history of drug/alcohol abuse (addiction) during the last 2 years Any grade 2 or higher toxicity in the hematology or biochemistry test results performed at the time of screening History of confirmed COVID-19 Acute or chronic hepatitis B and C Receiving prophylactic drug against tuberculosis History of syncope when seeing or giving blood Having splenectomy for any reason Any close contact with a definitively infected person with COVID-19 for a maximum of two weeks before the day of receiving the first dose

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **500**

Actual sample size reached: **500**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Block Randomization method with a block size of 4 was used to assign each participant to the intervention groups. The rand() function of Excel software will be used to generate random sequences within each block. After determining the allocated intervention, a non-repetitive four-digit random code was assigned to each participant. Assigned codes will be delivered to the eligible participants via software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, placebo will be used. Adjunct only IMP will be used as placebo. All people involved in the study will be blind to the type of IMP received except the epidemiologist responsible for unblinding. In cases of any serious adverse event or any trend in the occurrence of adverse events towards one of the groups, unblinding will occur by DSMB request. On other clinical occasions, unblinding could occur by the principal investigators' approval

Placebo

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

City

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Province

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Approval date

2021-06-07, 1400/03/17

Ethics committee reference number

IR.NREC.1400.003

Health conditions studied

1

Description of health condition studied

SARS-CoV-2

ICD-10 code

U07.1 COVI

ICD-10 code description

U07.1 COVID-19, virus identified

Primary outcomes

1

Description

Abnormal vital signs and anaphylactic reactions immediately after vaccination. Vital signs include body temperature, respiratory rate, heart rate, systolic and diastolic blood pressure before and immediately after vaccination

Timepoint

In the first three hours after each vaccine dose

Method of measurement

Sublingual temperature is measured using a digital thermometer. Heart rate and respiratory rate will be counted by the research staff in one minute. Blood pressure will be measured using a digital sphygmomanometer in a sitting position.

2

Description

Local adverse events within the first week post-vaccination including pain, tenderness, erythema and redness, and swelling and stiffness

Timepoint

In the first seven days after each vaccine dose

Method of measurement

Daily telephone contacts by the research team for seven days

3

Description

Systemic adverse event within the first week post-vaccination including nausea and vomiting, diarrhea, headache, fatigue, muscle pain, and other illnesses or clinical complications

Timepoint

In the first seven days after each vaccine dose and then monthly for up to six months.

Method of measurement

Telephone contacts by the research team

4

Description

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

Timepoint

on days zero, second injection day, two and four weeks after second injection and at 3, 6 months after the first vaccination.

Method of measurement

ELISA method

Secondary outcomes

1

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

Monthly follow-up by the research team

2

Description

Occurrence of COVID-19 disease

Timepoint

Two weeks after the second dose of the vaccine to study end

Method of measurement

PCR test

3

Description

Neutralizing antibody activity

Timepoint

on days zero, second injection day, two and four weeks after second injection and at 3, 6 months after the first

vaccination.

Method of measurement

Conventional SARS-CoV-2 virus neutralizing antibody test using a biosafety level III

4

Description

Cell-mediated immunity and safety of the immune response

Timepoint

on days zero, second injection day, two weeks after second injection and at 3, 6 months after the first vaccination.

Method of measurement

Absolute measurement of lymphocyte cell subpopulations (B, T, NK) and their ratio, measurement of T cell subpopulations (CD3 + CD4 +, CD3 + CD8 +), measurement of TNF-a and interleukins 4, 5, 2, 17, 6, 12, 17A, 17F, 21, 8 and 10.

5

Description

Abnormal laboratory findings including Hemoglobin, WBC, Lymphocytes cell, Neutrophils, Eosinophils, Platelets, ESR, CRP, LDH, CPK, RT-PCR for SARS-CoV-2, Sodium, Potassium, BUN , Creatinine, Alkaline phosphatase, ALT, AST, Bilirubin (total), U/A, Urine protein, Urine glucose, Urine RBC, IL-6

Timepoint

Seven days after each vaccination, IL-6 will be measured at day zero as well

Method of measurement

Each test will be performed using the appropriate kit

Intervention groups

1

Description

Intervention group: Two doses of 10 micro gram vaccine injected in the deltoid muscle (IM) at 14 days interval

Category

Prevention

2

Description

Control group:Two doses of placebo injected in the deltoid muscle (IM) at 14 days interval

Category

Placebo

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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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

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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 ForughiZadeh Moghadam

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Genetics

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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 and its necessity and scientific validity should be approved by the company

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