Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Phase 1, safety, immunogenicity and dose finding for two strengths of 0.5 × 10^6 and 2.5 × 10^6 (TCID50) inactivated SARS-CoV-2 vaccine FAKHRAVAC (MIVAC) injected in two schedules of two doses, 2 and 3 weeks apart in healthy adults aged 18-55 years: a randomized, double blind, placebo controlled, clinical trial

Protocol summary

Study aim

Dose finding, safety and immunogenicity of Covid 19 FAKHRAVAC (MIVAC) inactivated vaccine in healthy population 18-55 years

Design

Randomized, double blind, controlled trial with parallel design on 135 volunteers. Fifteen sentinels without blinding and 120 in 5 groups of 24, double blind and randomized

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-55 years; BMI 18-35; no abnormal clinical and laboratory findings; No current or previous infection with COVID-19; Use of safe methods of contraception; Signing informed consent form Exclusion criteria: Current acute or chronic illness requiring regular medical or surgical attention; High-risk occupations exposed with Covid-19; serving in obligatory military service; Breastfeeding; Pregnancy

Intervention groups

Group1: vaccine strength of 0.5*10^6, two doses at 14-day intervals Group2: vaccine strength of 2.5*10^6, two doses at 14-day intervals Group3: placebo, two doses at 14-day intervals Group4: vaccine strength of 0.5*10^6, two doses at 21-day intervals Group5: vaccine strength of 2.5*10^6, two doses at 21-day intervals Group6: placebo two doses at 21-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; Abnormal laboratory findings one week after each dose. Secondary outcomes: 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; Serum IgG level for SARS-CoV-2 to N and S antigens; Neutralizing antibody activity; Cell medicated immunity and safety of cell-mediated immune response.

General information

Reason for update

Correcting English translation

Acronym

IRCT registration information

IRCT registration number: **IRCT20210206050259N1**
Registration date: **2021-03-08, 1399/12/18**
Registration timing: **prospective**

Last update: **2022-06-20, 1401/03/30**
Update count: **4**

Registration date

2021-03-08, 1399/12/18

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

2021-03-10, 1399/12/20

Expected recruitment end date

2021-04-09, 1400/01/20

Actual recruitment start date

2021-03-16, 1399/12/26

Actual recruitment end date

2021-04-13, 1400/01/24

Trial completion date

2021-10-10, 1400/07/18

Scientific title

Phase 1, safety, immunogenicity and dose finding for two strengths of 0.5 × 10^6 and 2.5 × 10^6 (TCID50) inactivated SARS-CoV-2 vaccine FAKHRAVAC (MIVAC) injected in two schedules of two doses, 2 and 3 weeks apart in healthy adults aged 18-55 years: a randomized, double blind, placebo controlled, clinical trial

Public title

Safety, immunogenicity and dose finding for inactivated SARS-CoV-2 vaccine FAKHRAVAC (MIVAC)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian citizenship, and residing at a distance of 40-50 km from the study center The ability of participants to study and understand informed consent, preferably educational level of high school and higher Age between 18 and 55 years Body mass index between 18 and 35 kg/m2 Being healthy based on clinical and laboratory examinations Temperature less than or equal to 37.2°C sublingually measured by an electronic thermometer Negative IgG and IgM antibody titers against COVID-19 N antigen Negative RT-PCR test for COVID-19 Negative ELISA test for anti-HIV IgG Heart rate between 60 and 100 Systolic blood pressure between 90 and 140 mm Hg, diastolic blood pressure between 60 and 90 mm Hg Signing informed consent Accepting commitments to reduce the risk of COVID-19 infection in daily life Not pregnant Negative β-hCG pregnancy test on the screening and vaccination days The use of at least one safe method of contraception (condoms, oral contraceptive pills, IUD, Norplant capsule) for women of reproductive age 18 to 49 years Willingness to continue using at least one safe method of contraception (condoms, oral contraceptive pills, IUD, Norplant capsule) for women of reproductive age 18 to 49 years up to three months after the second vaccine dose Participants in the clinical trial should refrain from donating blood or plasma from the time of the first vaccine dose until three months after the second vaccine dose should not participate in another trial during the study period Expressing readiness to remain in the study for the entire study period Married men should use safe methods of contraception up to three months after the second vaccine dose

Exclusion criteria:

Any acute or chronic symptomatic disease requiring ongoing medical or surgical care at the screening day Healthcare workers Breastfeeding History of receiving any vaccine (whether investigational or non-investigational) within 30 days prior to the screening day History of receiving other investigational drugs within 60 days prior to the screening day History of receiving blood or any blood product or immunoglobulin within three months prior to the screening day History of Immunodeficiency disorders (suspected or definite) History of long-term use of immunosuppressive drugs (more than 14 consecutive days) within four months prior to the screening day History of long-term use (more than 14 consecutive days) of systemic corticosteroids (equivalent to 10 mg or more daily prednisolone) or high-dose inhaled steroids (more than 800 µg/day of beclomethasone dipropionate or equivalent) within four months prior to the screening day (excluding topical steroids) History of allergic diseases such as angioedema or anaphylaxis History of any known allergy to drugs or vaccines including aluminum phosphate and albumin History of known allergy to eggs History of autoimmune diseases Chemotherapy or radiotherapy in the last 5 years History of cancer in the last 5 years History of serious psychiatric illnesses History of blood disorders (dyscrasia, coagulation disorders, platelet deficiency or disorder, deficiency of blood factors) History of chronic obstructive pulmonary disease such as asthma diagnosed by a specialist History of ischemic heart disease currently treated by a cardiologist or receiving any cardiac interventions History of hypertension currently treated by a physician History of diabetes currently treated by a physician Congenital anomalies, growth retardation, genetic defects or severe malnutrition Individual or family history of chronic neurological diseases (including seizures and epilepsy) History of thyroid disease or Thyroidectomy Any history of substance or alcohol abuse in the past 2 years Abnormal hematological or biochemical test results at the time of screening History of confirmed COVID-19 Acute febrile illness at the time of vaccination History of allergy to acetaminophen History of acute or chronic hepatitis B and C History of pulmonary or extrapulmonary tuberculosis or receiving antituberculotic treatment Receiving tuberculosis prophylaxis History of faint in any encounter with needles or phlebectomy Splenectomy for any reason or history of abnormal spleen function Any close contact with a confirmed COVID-19 case up to two weeks before receiving the first vaccine dose Previous history of diseases such as SARS and MERS Not fit to participate in the trial (the decision is at the discretion of the chief investigator) People who are currently serving their obligatory military service in the Armed Forces

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

1

Groups that have been masked

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

Sample size
Target sample size: **135**
Actual sample size reached: **135**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the Block Randomization method with different block sizes was used to assign each participant to the intervention groups. The rand() function of Excel software will be used to generate a random sequence within each block. After determining the allocated intervention, each participant was assigned a non-repetitive four-digit random code. Assigned codes will be delivered to the eligible participants via study software.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, a placebo will be used. Adjuvant-only IMP will be used as a 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 with 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
Tehran
Province
Tehran
Postal code
7334144696
Approval date
2021-02-28, 1399/12/10
Ethics committee reference number
IR.NREC.1399.006

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 vaccination
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 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
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), Uric Acid, U/A, Urine protein, Urine glucose, Urine RBC

Timepoint

Seven days after each vaccination

Method of measurement

Each test will be performed using the appropriate kit

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

Method of measurement

PCR test

3

Description

Serum IgG level for SARS-CoV-2 N and S antigens

Timepoint

In the vaccination schedule 0-14: on days zero, 7, 14, 28, 42, 72 and months 3, 6. In the vaccination schedule 0-21: on days zero, 7, 14, 21, 35, 49 and months 3, 6.

Method of measurement

ELISA method

4

Description

Neutralizing antibody activity

Timepoint

In the vaccination schedule 0-14: on days zero, 14, 28, 42 and months 3, 6. In the vaccination schedule 0-21: on days zero, 21, 35, 49 and months 3, 6.

Method of measurement

Conventional SARS-CoV-2 virus neutralizing antibody test

5

Description

Cell-mediated immunity and safety of the immune response

Timepoint

In the vaccination schedule 0-14: on days zero, 14, 28, 42 and months 3, 6. In the vaccination schedule 0-21: on days zero, 21, 35, 49 and months 3, 6. This outcome will be measured on day zero and two weeks after the second injection for all volunteers and at other time points for 20% of the participants.

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.

Intervention groups

1

Description

Intervention group 1: Receiving two intramuscular doses of 0.5*10^6 (TCID50) strength of the vaccine equivalent to 5 µg/dose at a 14-days interval

Category

Prevention

2

Description

Intervention group 2: Receiving two intramuscular doses of 2.5*10^6 (TCID50) strength of the vaccine equivalent to 10 µg/dose at a 14-days interval

Category

Prevention

3

Description

Control group 1: Receiving two intramuscular doses of a placebo at a 14-days interval

Category

Placebo

4

Description

Intervention group 3: Receiving two intramuscular doses of 0.5*10^6 (TCID50) strength of the vaccine equivalent to 5 µg/dose at a 21-days interval

Category

Prevention

5

Description

Intervention group 4: Receiving two intramuscular doses of 2.5*10^6 (TCID50) strength of the vaccine equivalent to 10 µg/dose at a 21-days interval

Category

Prevention

6

Description

Control group 2: Receiving two intramuscular doses of a placebo at a 21-days interval

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Fakhra clinical trial center

Full name of responsible person
Mohsen Forooghizade Moghadam

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

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Web page address
http://www.fakhravac.ir

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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NO.9, Unit 3, Mirsharifi, Valiasr St.

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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
Private

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 Forooghizade Moghadam

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Genetics

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No. 12, Zomorod 1 block, Noor 1 St., Shahid Mahalati Town

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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

Position
Associate professor

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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

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biology

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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
Yes - There is a plan to make this available

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
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