Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A double-blind, randomized, placebo-controlled Phase II clinical trial to evaluate the immunogenicity and safety of covid-19 recombinant RBD protein vaccine (80 microgram) of Plasma Darman Sarve Sepid Co. in healthy population.

Protocol summary

Study aim
to determine the immunogenicity and safety of COVID-19 recombinant receptor binding domain (RBD) protein vaccine in healthy population

Design
Clinical trial with control group with parallel groups, double-blind, randomized, phase two on 300 volunteers

Settings and conduct
This double-blind study (volunteers and outcome assessors) with placebo will be performed on 300 healthy volunteers at Baqiyatallah Hospital in Tehran, Shahid Soleimani Clinical Trial Center . Candidates received a random dose of 80 micrograms of vaccine or placebo, received the vaccine on days 0, 21 and 35, and were followed up until day 49 for side effects, humoral and cellular immunity. All people will be followed up for a long time after the end of the study until day 360.

Participants/Inclusion and exclusion criteria
Healthy 18-40 years, the ability to understand the study, signing the informed consent, not being pregnant, Main exclusion criteria: Positive PCR test, symptoms consistent with COVID-19, history of COVID-19 disease in the last month, abnormal paraclinical findings, history of allergy to the vaccine, neurologic disease, immunodeficiency, coagulopathy, psychiatric and other chronic diseases, Receiving live vaccine in one month or other vaccines in 14 days before inoculation

Intervention groups
Participants are randomly assigned to the following groups: 1- Receiving the recombinant vaccine (80 micrograms) intramuscularly (deltoid muscle) on days 0, 21 and 35 (240 people) 2- Receiving placebo (buffer + adjuvant) intramuscularly (deltoid muscle) on days 0, 21 and 35 (60 people)

Main outcome variables
The titer of antibody (RBD), the occurrence of SARS-COV-2 infection, measurement of cellular immunity. occurrence of any side effects after injection, during 7, 125 days, and a year.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210620051639N2**
Registration date: **2021-10-11, 1400/07/19**
Registration timing: **prospective**

Last update: **2021-10-11, 1400/07/19**
Update count: **0**

Registration date
2021-10-11, 1400/07/19

Registrant information

Name
Jafar Salimian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8755 4530

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-12, 1400/07/20

Expected recruitment end date
2021-12-11, 1400/09/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A double-blind, randomized, placebo-controlled Phase II clinical trial to evaluate the immunogenicity and safety of covid-19 recombinant RBD protein vaccine (80 microgram) of Plasma Darman Sarve Sepid Co. in healthy population.

Public title
Clinical trial of Noora vaccine
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy persons, 18-40 years old, Without uncontrolled underlying disease
Exclusion criteria:
History of Covid-19 disease in the past month, positive coronavirus PCR test, uncontrolled underlying disease, T Important surgical history, receiving corona vaccine
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization process in this study will be done in one step and a random chain will be created. For this purpose, 72 random block sequences with size 5 are produced so that for every 4 volunteers receiving active vaccine, 1 volunteer will receive a placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
Each dose of vaccine is packaged separately and has an identification number. Vaccine boxes and placebo are offered in exactly the same appearance and packaging, which will blind the participants, researchers and outcome assessors. After using the vaccine, the abbreviation of the study participant and the date of vaccination are written in the outer packaging box and the activity label is recorded on the main sheet. Personnel check all information before injection. During the study, all outer packing boxes will be archived and maintained.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Research Ethics Committees
Street address
13th floor, Block A, Ministry of health, Simaye Iran street, Shahrake ghods
City
Tehran
Province
Tehran
Postal code
1417993337
Approval date
2021-10-06, 1400/07/14
Ethics committee reference number
IR.NREC.1400.009

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
U07.1 COVID-19, virus identified

Primary outcomes

1

Description
IgG antibody against Receptor Binding Domain (RBD) protein
Timepoint
in days 0, 35, 49, 125, 215 after injection of the first dose of vaccine
Method of measurement
based on ELISA method and seroconversion rate (proportion of individuals with at least twofold and fourfold increases) and Geometric Mean Titer (GMT)

2

Description
Cellular immunity response against recombinant vaccine RBD protein
Timepoint

in days 0 and 49 after injection of the first dose

Method of measurement

determining Th1 or Th2 dominance based on levels of IL-4، IL-10، IL-12، و INFγ with ELISA measurement, and levels of CD3، CD4، CD8 with INFγ based on flow cytometry measurement

3

Description

Measurement of neutralizing Antibody based on virus neutralizing test (VNT)

Timepoint

in day 49 after injection of the first dose

Method of measurement

Based on the cell culture and inhibition of virus entry (Neutralizing titer)

Secondary outcomes

1

Description

Local adverse event (s) (pain, redness, stiffness, swelling, skin rash, burning and itching)

Timepoint

30 min to 7 days after injection

Method of measurement

close monitoring

2

Description

Adverse systemic events (fever, headache, chills, diarrhea, vomiting, muscle aches, joint pain, shortness of breath, fatigue, allergic reactions, etc.) based on the severity, duration and maximum severity of the complication

Timepoint

0-7 days after each injection

Method of measurement

Examination, history, and report of the study participant based on the Vaccine Adverse Event Reporting System

3

Description

Adverse laboratory event (s) (biochemical or hematological) based on FDA scoring

Timepoint

in day 49 after vaccination

Method of measurement

based on FDA score

4

Description

Any serious adverse event, medically attended adverse event, or adverse event of interest

Timepoint

0-125 days after each injection

Method of measurement

Examination, history, and report of the study participant based on the Vaccine Adverse Event Reporting System

Intervention groups

1

Description

Intervention group: receiving 80 micrograms of RBD protein recombinant SARS-CoV-2 vaccine in days 0, 21, and 35; intramuscular (deltoid muscle)

Category

Prevention

2

Description

Control group: the placebo group will receive an intramuscular injection (in the deltoid muscle) consisting of buffer and adjuvant only, on days 0, 21, and 35

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ghassem Soleimani Clinical Trial Center

Full name of responsible person

Dr. Hassan Abolghasemi

Street address

Ŝhahid Ghassem Soleimani Clinical Trial Center, Baqiyatallah University of Medical Sciences,Shahid Nosrati Alley, Sôuth Sheykh Bahaei, Mollasadra Street , Tehran,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Jafar Salimian

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Baqiyatallah University of Medical Sciences,Shahid Nosrati Alley, Sôuth Sheykh Bahaei, Mollasadra Street , Tehran,

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Grant name

Grant code / Reference number

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

Title of funding source
Bagheiat-allah University of Medical Sciences

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr. Hassan Abolghasemi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No plans to release patient data

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

Data will be available to regulatory bodies and the ethics committee

When the data will become available and for how long

The protocol and results will become available to the public after completion of the study.

To whom data/document is available

The regulatory body and the ethics committee will have access to the study data. The monitoring team will have access to the study data during the conduct. DSMB will have access to the study data and results in predefined timelines and decides about the continuation of the study.

Under which criteria data/document could be used

With the permission of the sponsor and the approval of regulatory

From where data/document is obtainable

The study sponsor is responding to this request

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

Relevant applications will be provided to the requesting researcher in the form of a joint project after review and approval by the relevant authorities. Normally between 3 to 5 working days

Comments