# 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**

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Iran (Islamic Republic of)

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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

**Street address**

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

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## 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**