

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2022

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)

Phone

+98 21 8755 4530

Email address

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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, and INF γ with ELISA measurement, and levels of CD3, CD4, CD8 with INF γ 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

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

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Phone

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Email

H.abolghasemi.ha@gmail.com

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, South 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

Street address

Baqiyatallah University of Medical Sciences, Shahid Nosrati alley, Shiekh Bahaei st., Mollasadra st,

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for updating data**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Hassan Abolghasemi

Position

Professor

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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