

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

Phase 3 Clinical Trial to evaluate the Immunogenicity and Safety of Covid19 Recombinant RBD Protein Vaccine (Noora Vaccine) as a Booster Vaccine after injection of existing Vaccines in IRAN

Protocol summary

Study aim

Evaluation of Immunogenicity and safety of Noora vaccine as a booster.

Design

This clinical trial is designed as a hybrid (in the form of two separate trials) in phase 3: "First A randomized, double blind clinical trial with two parallel groups and a single center with a sample size of 300 people. Second A multicenter and single arm clinical trial comparing before and after injection of booster vaccine with a sample size of 10000 people.

Settings and conduct

The first part in the single center of Shahid Soleimani will be randomly double blind with parallel groups to check the immunogenicity. Blinding ratio will be 1: 2 and the volunteer, researcher and executive staff are unaware of the nature of the injection. The second ward will be in one of the 10 affiliated centers of Baqiyatallah Hospital, before and after. After injection, possible allergic reactions and other reactions will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: over 18 years of age, candidates who have received two identical doses of the specified approved vaccine by MOH, and at least 3 months after the second dose, fully understand the provisions of the consent form and sign it. Exclusion criteria include: COVID19 infection in the past two months, quarantine, history of certain diseases, medication received in the last 3 months, receiving immunoglobulin or blood products in the previous 3 months, pregnant women Or breastfeeding or intending to pregnancy

Intervention groups

Including two intervention groups 1) Injection of 80 µg of recombinant RBD protein vaccine 2) Injection of a placebo dose

Main outcome variables

Primary Outcomes: Comparison of antibody levels in a sample of 300 volunteers on days 0 and 21 after injection. Cell immune response to booster dose and measurement of neutralized antibody level in 90 subgroups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210620051639N3**

Registration date: **2021-12-23, 1400/10/02**

Registration timing: **prospective**

Last update: **2021-12-23, 1400/10/02**

Update count: **0**

Registration date

2021-12-23, 1400/10/02

Registrant information

Name

Jafar Salimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 4530

Email address

jafar.salimian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-26, 1400/10/05

Expected recruitment end date

2022-04-04, 1401/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phase 3 Clinical Trial to evaluate the Immunogenicity and Safety of Covid19 Recombinant RBD Protein Vaccine (Noora Vaccine) as a Booster Vaccine after injection of existing Vaccines in IRAN

Public title

Phase 3 Clinical Trial to evaluate the Immunogenicity and Safety of Covid19 Recombinant RBD Protein Vaccine (Noora Vaccine) as a Booster Vaccine after injection of existing Vaccines in IRAN

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 years and older Candidates who have received two identical doses of the available vaccine (Sinopharm, CovIran Barakat, AstraZenka) and at least 3 months (at least 90 days) have passed since the second dose The candidate is able to fully understand the provisions of the informed consent form and sign it before entering the study

Exclusion criteria:

SARS CoV 2 infection (clinically significant or rtPCR document) Approved or suspected COVID 19 in the last two months Going through home quarantine due to suspicion of having an exposure to a patient with Corona History of severe allergic reactions Chronic kidney, liver and various malignancies Acute bacterial infection in the last 7 days Known cases of immunodeficiency, HIV, or autoimmune diseases Receiving immunosuppressive drugs or corticosteroids in the last 3 months Receiving immunoglobulin or blood products during the three months prior to vaccination Pregnant or Breastfeeding women or those who plan to become pregnant during the study period

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

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

Sample sizeTarget sample size: **10300****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, Randomization process in immunogenicity assessment section is performed one step before the

onset of recruitment. For this purpose, 60 random block sequences with size 6 will be produced so that for every 4 volunteers receiving the recombinant vaccine, 2 volunteers will receive placebo. There is no randomization process in the safety assessment section which will be performed before and after.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding process in the immunogenicity assessment section of this study, which will be performed on a sample size of 300 people, is performed in a double-blind manner. For this purpose, the placebo is exactly the same as the vaccine and is prepared by the manufacturer with the same volume, color and other specifications and will be labeled by an independent group based on randomization codes. Obviously, the researchers, the evaluation team of the volunteers, the vaccinators and the volunteers will be completely unaware of the type of product received. In the safety assessment section (on a sample size of 10000 people), the study will be open labeled and the blinding process will not be used.

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

13th floor, Block A, Ministry of health, Simaye Iran street, Shahrake ghods

City

Tehran

Province

Tehran

Postal code

1417993337

Approval date

2021-12-22, 1400/10/01

Ethics committee reference number

IR.NREC.1400.016

Health conditions studied**1****Description of health condition studied**

Covid 19

ICD-10 code

U07.1

ICD-10 code description
COVID 19, virus identified

Primary outcomes

1

Description

The level of specific IgG antibody against RBD protein in days 0 and 21 after booster injection based on GMI, GMT and seroconversion rate (increase at least 4 times in antibody titer) in Shahid Soleimani Clinical Trial Center (sample of 300 people).

Timepoint

in days 0 and 21 after booster injection

Method of measurement

The level of specific IgG antibody against RBD protein based on GMI, GMT and seroconversion rate (increase at least 4 times in antibody titer) .

2

Description

Cellular immune response to booster dose based on measurement of IL 4 and INF γ levels using ELISA method on days 0 and 21 after injection (subgroup of 90 people)

Timepoint

in days 0 and 21 after booster injection

Method of measurement

Cellular immune response to booster dose based on measurement of IL 4 and INF γ levels using ELISA method .

3

Description

Measurement of neutralizing antibody level by neutralization test method Virus (subgroup of 90 people)

Timepoint

in days 0 and 21 after booster injection

Method of measurement

Measurement of neutralizing antibody level by neutralization test method Virus.

Secondary outcomes

1

Description

Any reaction within 30 minutes after booster dose injection

Timepoint

within 30 minutes after booster dose injection

Method of measurement

Data collection and recording by the nurse or physician based on the participating condition within 30 minutes after injection at the vaccination site

2

Description

Occurrence of local adverse event (s) (pain, redness,

stiffness, swelling, skin rash, burning and itching) or systemic (fever, headache, chills, diarrhea) Vomiting, muscle pain, joint pain, shortness of breath, fatigue, allergic reactions, etc.) based on the severity, duration and maximum severity of the complication within 3 and 7 days after injection of the booster dose

Timepoint

within 3 and 7 days after injection of the booster dose

Method of measurement

Experts contact participants and record possible side effects.

3

Description

Incidence of adverse event (s) Systemic (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 within 28 days after booster dose

Timepoint

within 28 days after booster dose

Method of measurement

Experts contact participants and record possible side effects.

4

Description

Incidence of adverse event (s) Systemic (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 within 60 days after booster dose as a complementary outcome

Timepoint

within 60 days after booster dose

Method of measurement

Experts contact participants and record possible side effects.

5

Description

Level of IgG antibody specific against RBD protein in 3 and 6 months after booster dose injection and seroconversion rate (increase at least 4 times in antibody titer) in the vaccine group in Shahid Soleimani Clinical Trial Center (group of 200 people) as a complementary outcome

Timepoint

in 3 and 6 months after booster dose injection

Method of measurement

collecting blood samples of vaccine participants (200 people) in Shahid Soleimani Trial Center.

Intervention groups

1

Description

Intervention Group: Injection of a dose of 80 micrograms of recombinant RBD protein vaccine intramuscularly

(deltoid muscle) in 10000 participants in affiliated centers of Baqiyatallah Hospital and 200 participants in Shahid Soleimani Clinical Trial Center

Category

Prevention

2

Description

Control group: Injection of a placebo intramuscularly (deltoid muscle) in 100 participants in Shahid Soleimani Clinical Trial Center

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid 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

2

Recruitment center

Name of recruitment center

Shahid Saleh Mahdavi Majd Vaccination Cumulative center

Full name of responsible person

Mr. Hasan Kardari

Street address

Next to Hazrat Fatemeh Caring Center, Zafar Square, Shahrake Mahalati

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3

Recruitment center

Name of recruitment center

Shohadaie Salamat vaccination cumulative center

Full name of responsible person

Mr. Ali Heidari

Street address

Across from Post office, Mofateh street, Shahid beheshti street

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1531818811

Phone

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Email

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4

Recruitment center

Name of recruitment center

Imam Hossein Boarding Clinic

Full name of responsible person

Mr. Ali Bakhtiary Zadeh

Street address

Imam Hossein University Residential Complex, Shahid Babaei Highway

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5

Recruitment center

Name of recruitment center

Khavaran Cultural cumulative vaccination center

Full name of responsible person

Mr. Hossein Moradi

Street address

Khavaran Street, Khavaran Cultural Center

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Anabestaniali1349@yahoo.com

6

Recruitment center

Name of recruitment center

Azadi Stadium Vaccination Center

Full name of responsible person

Ms. Ashraf Roohi

Street address

East side of Azadi Stadium, Gate number 17

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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, South Sheykh Bahaei, Mollasadra Street
, Tehran,

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1435916471

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jafar.salimian@gmail.com

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

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Full name of responsible person

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Hematology and Oncology

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Email

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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

There is not 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

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