Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Dec 2023

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)

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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
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target 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 ibased 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 INFγ 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 INFγ 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, Sôuth 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 Mahdavie 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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1955877143

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Email

ahad389@yahoo.com

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

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4

Recruitment center

Name of recruitment center

Imam Hossein Boarding Clinic

Full name of responsible person

Mr. Ali Bakhtiary Zadeh

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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

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6

Recruitment center

Name of recruitment center
Azadi Stadium Vaccination Center

Full name of responsible person
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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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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 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
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