Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Immunogenicity and Safety of intranasal Razi Cov Pars as a booster dose in adult population; randomised, double blind, placebo controlled clinical trial

Protocol summary

Study aim
Immunogenicity and Safety of intranasal Razi Cov Pars as a booster dose in adult population

Design
This is a randomized double blind placebo controlled parallel group clinical trial. In this study we explore the immunogenicity of intranasal Razi Cov Pars as a booster dose. Stratified block randomization will be used. The type of the vaccine in the primary vaccination will be used to define the strata. An adjuvant only preparation will be used as placebo.

Settings and conduct
Razi Vaccine and Serum Research Institute Beheshti Ave, Hesarak, Karaj, Alborz Province

Participants/Inclusion and exclusion criteria
Main inclusion criteria: Age 18 years and older, Minimum 5 and maximum 9 months interval from the last vaccine dose, no history of confirmed Covid-19 illness during the first 5 months. Major exclusion criteria: History of allergic reactions after receiving any previous Covid-19 vaccines or any other drug or vaccine, Having any acute or chronic illness requiring continuous ongoing medical or surgical care within the last month

Intervention groups
Intervention group: One intranasal dose of 10 microgram per 200 micro liter of Razi Cov Pars recombinant protein vaccine; Control group: One intranasal dose of placebo

Main outcome variables
Serum levels of specific IgG antibodies against S and RBD antigens two weeks after the intranasal booster dose by ELISA method, Serum levels of specific IgA antibodies against RBD antigen, levels of specific IgG/IgA antibodies against S and RBD in saliva and nasal mucosa, Abnormal vital signs and anaphylactic reactions before and immediately after vaccination; The number and percentage of systemic adverse reactions within the first week post-vaccination, Number and percentage of Severe Adverse events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSAR) and Medically Attended Adverse Events (MAAEs) Up to one month after receiving the booster dose.

General information

Reason for update
reporting actual start and end dates and completion date, amending inclusion criteria

Acronym

IRCT registration information
IRCT registration number: **IRCT20201214049709N6**
Registration date: **2022-11-29, 1401/09/08**
Registration timing: **prospective**

Last update: **2024-01-22, 1402/11/02**
Update count: **2**

Registration date
2022-11-29, 1401/09/08

Registrant information

Name
Ali Eshaghi

Name of organization / entity
Razi Vaccine and Serum Research Institute

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-03, 1401/09/12

Expected recruitment end date
2023-02-27, 1401/12/08
Actual recruitment start date
2023-01-03, 1401/10/13
Actual recruitment end date
2023-02-22, 1401/12/03
Trial completion date
2023-04-08, 1402/01/19

Scientific title
Immunogenicity and Safety of intranasal Razi Cov Pars as a booster dose in adult population; randomised, double blind, placebo controlled clinical trial

Public title
Immunogenicity and Safety of intranasal Razi Cov Pars as a booster dose
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having Iranian citizenship or in the case of foreign nationals with a legal residence permit Age 18 years and older History of full vaccination with one of the following vaccines: Sinopharm, Razi Cov Pars, Pastocovac, Spikogen, AstraZeneca, Fakhra, or Barkat at least 5 months before the study 5 months interval between the last vaccine dose and the current study participation In the last six months, the person has not had a confirmed Covid-19 disease based on laboratory evidence or confirmed by a physician Signing a written informed consent form Using at least one reliable contraceptive method (condom, oral contraceptive pills, intrauterine contraceptive device, IUD, Norplant capsule) for women of reproductive age 18 to 49 years until 3 months after receiving the booster dose Negative pregnancy test (baby check) on the day of vaccination
Exclusion criteria:
History of allergic reactions after receiving any previous Covid-19 vaccines or any other drug or vaccine Having any acute or chronic illness requiring continuous ongoing medical or surgical care within the last months History of severe cardiovascular disease such as heart failure, or hospitalization due to heart disease within the last year Pregnancy declared by the participant based on the first day of the last menstrual period (LMP) Breastfeeding History of receiving any vaccine within 14 days of receiving the intranasal booster dose Received blood and/or any blood products and/or immunoglobulins within three months prior to the intranasal booster dose Diagnosed (suspected or confirmed) with immunocompromising illneses, history of long-term use of immunosuppressive drugs, including history of long-term use of systemic corticosteroids equivalent to 10 mg or more daily prednisolone for more than 14 consecutive days with the exception of topical steroids within the last 4 months Recent diagnosis or treatment of cancers except basal cell carcinoma and In-situ cervical cancer History of uncontrolled serious psychiatric illnesses History of blood disorders (dyscrasia, coagulopathy, platelet deficiency or disorder, or deficiency of blood clotting factors) History of chronic neurological diseases (including seizures and epilepsy) Current substance or alcohol abuse Acute febrile illness at the time of receiving the booster dose Splenectomy for any reason Close contact with a confirmed COVID-19 case within two weeks before participating in the current study Continued use of anticoagulants such as coumarin and related anticoagulants (such as warfarin) or new oral anticoagulants / antiplatelet agents. Note: Less than 325 mg of aspirin per day as prophylaxis is allowed Chronic unstable diseases in the last 4 weeks, including hospitalization due to surgery, deterioration of one of the organ system's function, a need to add new drugs or serious dose adjustments for existing drugs
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **206**
Actual sample size reached: **193**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, stratified block randomization method with variable block sizes of 4 and 6 were used to assign each participant to the intervention groups. The rand() function of Excel software were used to generate the random sequence within each block. After determining the allocated intervention, a non-repetitive eight-digit random code was assigned to each participant.This random code is a compilation of strata number, the number assigned to each participant and the "RIB" character and study participants will be identified by these codes during the study. Each strata includes participants that have received one of the seven vaccines (Sinopharm, Razi Cov Pars, Pastocovac, Spikogen, AstraZeneca, Fakhra, or Barkat) used as part of Iranian National Vaccination program as their primary vaccination.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, blinding will be achieved by using placebo which is the adjuvant only preparation identical in volume, appearance and packaging to the vaccine and will be used intranasally the same as the vaccine. In this study participants and all the research team members are unaware of the type of intervention. The study epidemiologist will keep the key to the random codes and will unblind any particular participant or participants if necessary.
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

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

7334144696

Approval date

2022-11-26, 1401/09/05

Ethics committee reference number

IR.NREC.1401.004

Health conditions studied

1

Description of health condition studied

SARS-CoV-2

ICD-10 code

COVID-19

ICD-10 code description

U07.1

Primary outcomes

1

Description

Serum levels of specific IgG antibodies against S and RBD antigens

Timepoint

2 weeks after the intranasal booster dose

Method of measurement

ELISA method

Secondary outcomes

1

Description

Serum levels of specific IgA antibody against RBD antigen

Timepoint

2 weeks after the intranasal booster dose

Method of measurement

ELISA method

2

Description

levels of specific IgG and IgA antibodies against S and RBD antigens in saliva and nasal mucosa.

Timepoint

2 weeks after the intranasal booster dose

Method of measurement

ELISA method

3

Description

Abnormal vital signs and anaphylactic reactions before and immediately after vaccination: number and percentages of participants who develop abnormal vital signs within half an hour of receiving the vaccine will be recorded. Abnormal vital signs include temperature, respiratory rate, heart rate, systolic and diastolic blood pressure. Anaphylaxis is defined as an immediate systemic hypersensitivity simultaneously involving two systems. Anaphylactic reactions include: erythema, pruritus, urticaria and angioedema, bronchospasm, laryngeal edema, dizziness, hypotension, nausea, shortness of breath, wheezing, arrhythmia, cyanosis, vomiting, diarrhea, abdominal pain and will be checked up to half an hour after vaccine booster dose.

Timepoint

Before vaccination and half an hour after vaccination

Method of measurement

Clinical examination

4

Description

The number and percentage of systemic adverse reactions within the first week post-vaccination (including pain, tenderness, erythema / redness, swelling and stiffness, itching) that will be assessed based on the severity score, duration and peak intensity.

Timepoint

Daily, within the first week after intranasal booster dose

Method of measurement

Via mobile application, study staff will contact participants who fail to fill their application and complete a local adverse reaction form on their behalf.

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Description

Number and percentage of Severe Adverse events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSAR) and Medically Attended Adverse Events (MAAEs) Up to one month after receiving the booster dose.

Timepoint

Up to one month after the intranasal booster dose

Method of measurement

Active follow-up on a weekly basis will be done by phone. Report of an adverse event could also be made via the mobile application. There will be a physician available 24/7 in the follow up center and all the reported events will be recorded and followed up by the staff in the center.

Intervention groups

1

Description
Intervention group: One intransal dose of 10 microgram per 200 microliter of Razi Cov Pars recombinant protein vaccine
Category
Prevention

2

Description
Control group: One intransal dose of placebo
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Vaccine and Serum Research Institute
Full name of responsible person
Ladan Mokhberossafa
Street address
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Email
lady.Katbi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razi Vaccine and Serum Research Institute
Full name of responsible person
Ali Eshaghi
Street address
Beheshti Ave, Hesarak, Karaj, Alborz Province
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3197619751
Phone
+98 26 3457 0038
Email
a.Eshahghi@rvsri.ac.ir
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Razi Vaccine and Serum Research Institute
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
Razi Vaccine and Serum Research Institute
Full name of responsible person
Mohammad Hossein Fallah Mehrabadi
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Iran University of Medical Sciences
Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Corner of Mansouri, Niayesh, Satarkhan Av, Tehran

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Person responsible for updating data

Contact

Name of organization / entity

Razi Vaccine and Serum Research Institute

Full name of responsible person

Ladan Mokhberossaf

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Deidentified IPD related to outcome will be shared

When the data will become available and for how long

The access period will begin once the study is complete and the main results have been published in peer reviewed journals.

To whom data/document is available

The data that have been published in peer reviewed journals, will be available just for academic researchers.

Under which criteria data/document could be used

The proposed study protocol should be submitted to RAZI vaccine and serum research institute and approved by its scientific and technical committee.

From where data/document is obtainable

After publishing the article researchers can submit their request to Dr. Mohammad Hossein Fallah at the following email address (mhf2480@yahoo.com).

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

Data will be made availabe after consideration and approval by the relevant authorities from Razi Vaccine and Serum Research Institute.

Comments