Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 2026

Comparison of immunogenicity and safety of Razi Cov Pars and Sinopharm booster doses in adults 18 years of age and older who have primarily vaccinated with Sinopharm: a parallel 2 arms, randomised, double blind clinical trial

Protocol summary

Study aim
Comparison of immunogenicity and safety of Razi Cov Pars and Sinopharm booster doses in adults 18 years of age and older who have primarily vaccinated with Sinopharm: a parallel 2 arms, randomised, double blind clinical trial

Design
A randomized, double blind, parallel groups, controlled trial on 500 participants.

Settings and conduct
Study setting: 1. Razi Vaccine and Serum Research Institute, Karaj 2. Rasoul hospital, Tehran

Participants/Inclusion and 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 complete vaccination with Sinopharm vaccine at least 90 days and at most 195 days from the last vaccination. Main exclusion criteria: History of allergic diseases such as angioedema or anaphylactic reactions after receiving previous COVID vaccines (including urticaria and fever); Any current or new diagnosis of acute or chronic illness requiring continuous ongoing medical care; Pregnancy and lactation; Immunodeficiency diseases (Suspected and Definitive); 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); Acute febrile illness at the time of booster vaccine injection.

Intervention groups
One group will receive Razi Cov Pars, and the other Sinopharm vaccine (a single dose).

Main outcome variables
Neutralizing antibody activity 2wks, 3 and 6 month after injection; Abnormal vital signs and anaphylactic reactions; Local and systemic reactions within the first week after booster dose; SAEs, SUSARs, MAAEs; IgG level for SARS-CoV-2, S1, RBD antigens; Cell-mediated immune response (lymphoproliferation, INFy, TNFa, CD3/CD8 ratio) following stimulation by S antigen.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201214049709N4**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **prospective**

Last update: **2021-11-29, 1400/09/08**
Update count: **0**

Registration date
2021-11-29, 1400/09/08

Registrant information

Name
Ali Eshaghi
Name of organization / entity
Razi Vaccine and Serum Research Institute
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-30, 1400/09/09
Expected recruitment end date
2022-02-28, 1400/12/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of immunogenicity and safety of Razi Cov Pars and Sinopharm booster doses in adults 18 years of age and older who have primarily vaccinated with Sinopharm: a parallel 2 arms, randomised, double blind clinical trial

Public title
Comparison of immunogenicity and safety of Razi Cov Pars and Sinopharm booster doses
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having Iranian citizenship; Age 18 years and older; Having history of full vaccination with Sinopharm vaccine (two doses) 75 to 195 days from the last vaccination; Signing an informed consent form; For females of childbearing age 18 to 49 years: use of at least one effective method of contraception (condom, oral contraceptive pills, intrauterine device, norplant capsule) and willing to continue up to two month after the booster dose.
Exclusion criteria:
History of allergy to drugs or vaccines (e.g urticaria and fever); Any current or new diagnosis of acute or chronic illness requiring continuous ongoing medical care; Severe cardiovascular disease; Breastfeeding; History of receiving any vaccine within 14 days before receiving the booster dose; History of diseases resulting in immunosuppression (suspected and definite); 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) with the exception of topical steroids (more than 14 consecutive days) within the past 4 months; History of uncontrolled serious psychiatric illnesses; History of chronic neurological diseases (including seizures and epilepsy)؛ Acute febrile illness at the time of booster vaccine injection; Splenectomy for any reason; Close contact with a confirmed COVID-19 case within two weeks before the booster dose; 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 is allowed as prophylaxis; Recent diagnosis or treatment of cancers except basal cell carcinoma and In-situ cervical cancer; Received blood and/or any blood products and/or immunoglobulins within three months preceding the booster dose; History of blood disorders (dyscrasia, coagulopathy, platelet deficiency or disorder, or deficiency of blood clotting factors); Current substance or alcohol abuse; Pregnancy based on the participant's statement and the time of the first day of the last menstrual period and negative pregnancy test (baby check) on the day of vaccination; History of COVID -19 based on laboratory or clinical evidence after primary vaccination; Chronic unstable diseases in the last 4 weeks, including hospitalization due to surgery, deterioration of one organ function, the need to add new drugs or serious dose adjustments to existing drugs.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

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

Sample size
Target sample size: **500**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, stratified block randomization method with block size of 4 was used to assign each participant to the intervention groups. The rand() function of Excel software were used to generate random sequence within each block. After determining the allocated intervention, a non-repetitive five-digit random code was assigned to each participant.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the control group will receive the Sinopharm vaccine, which has different packaging and shape compared to Razi Cov Pars. Therefore, implementation of blinding will be done by a person who will be responsible for this. This is the only person who will not be blind to the intervention given. Once the participant becomes eligible to receive the vaccine, a concealment/randomization code will be assigned to the volunteer and the vaccine type will be displayed on the screen of the vaccinator until the inoculation is confirmed.
Placebo
Not used
Assignment
Parallel
Other design features
Alongside the main study, four additional groups of participants, 25 each, who have been primarily vaccinated by either of Astrazeneca, Sputnik V, Razi CoV Pars, and Pastocovac vaccines within the last 4 to 6 month, will receive one dose of Razi CoV Pars.

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
2021-11-28, 1400/09/07

Ethics committee reference number
IR.NREC.1400.013

Health conditions studied

1

Description of health condition studied
SARS-CoV-2

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Neutralizing antibody activity

Timepoint
On day zero, two weeks, 3 and 6 months after the booster dose injection

Method of measurement
SARS-CoV-2 virus neutralizing antibody titter measured in bio-safety level III lab using conventional method

Secondary outcomes

1

Description
Serum levels of specific IgG antibodies against S1, RBD antigens

Timepoint
On day zero, two weeks, 3 and 6 months after the booster dose vaccine

Method of measurement
ELISA method

2

Description
The cell-mediated immunity will be evaluated by counting the number of CD3, CD4 and CD8 cells and joint calculation of CD3 and CD4 and CD3 and CD8 . IFN-γ, TNF-α, and interleukins 2, 4, 6, and 17 will also be measured. It will be will be assessed in 20 members of the selected group. Summary of the measures performed in this section are as follows: 1- Assessment of CD4 to CD8 cell proportions after stimulation of PBMC (Peripheral Blood Mononuclear Cells) by inactivated virus and recombinant spike protein using flow cytometry 2- Assessment of specific proliferation of PBMC cells stimulated by inactivated virus and recombinant spike protein using flow cytometry 3 - Assessment of TH1 and TH2 specific cellular immunity after PBMC stimulation in vaccinated individuals with recombinant spike protein to determine the levels of interferon-gamma, interleukin-4, tumor necrosis factor-alpha and interleukin 6 using ELISpot and ELISA kit.

Timepoint
On day zero, two weeks, 3 and 6 months after the booster dose vaccine

Method of measurement
Immunologic lab tests

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 local adverse reaction 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 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.

5

Description
The number and percentage of systemic adverse reaction within the first week post-vaccination (including nausea and vomiting, diarrhea, headache, fatigue, muscle pain) that will be assessed based on the severity score, duration and peak intensity.

Timepoint
Seven days after booster dose (Days 0-7) daily assessment.

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

6

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

Timepoint
Up to one month after the booster dose

Method of measurement
Via mobile application. There will be a 24-7 follow up center with physicians available all the time.

Intervention groups

1

Description
Intervention group 1: Participants in this group will receive one doses (IM) of RAZI recombinant spike protein vaccine (day 0)

Category
Prevention

2

Description
Intervention group 2: Participants in this group will receive one doses (IM) of Sinopharm vaccine (day 0).

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasoul Akram Hospital

Full name of responsible person
Ladan Mokhberossafa

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Corner of Mansouri, Niayesh, Satarkhan Av, Tehran

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Tehran

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2

Recruitment center

Name of recruitment center
Razi Vaccine and Serum Research Institute

Full name of responsible person
Dr Mojtaba Noofeli

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Hesarak, Beheshti Ave

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3197619751

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Razi Vaccine and Serum Research Institute

Full name of responsible person
Ali Eshaghi

Street address
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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

Epidemiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Saeid Kalantari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ladan Mokhberossaf

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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lady.Katbi@yahoo.com

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