# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
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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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**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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## 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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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**

Razi Vaccine and Serum Research Institute

**Full name of responsible person**

Ladan Mokhberossaf

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

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## 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**