# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Nov 2026

## Safety and Immunogenicity of Razi Cov-2 recombinant Spike protein vaccine (RAZI Cov Pars) in healthy children and adolescents aged 5-17 years; single group, open label study

## Protocol summary

**Study aim**
Evaluation of safety and immunogenicity of recombinant protein sub-unit COVID-19 vaccine (Razi Cov Pars) in healthy children and adolescents aged 5-17

**Design**
Single group, open label study will be conducted on 420 volunteers

**Settings and conduct**
Recruitment centers: Razi Vaccine and Serum Research Institute, Hesarak, Karaj

**Participants/Inclusion and exclusion criteria**
Important inclusion criteria: participants legal guardian should be able to read and write; Age between 5-17 years; Negative RT-PCR tests for COVID-19; Signed informed consent; Non pregnant or lactating (women); Important exclusion criteria: Any ongoing, symptomatic, uncontrolled, acute or chronic illness requiring medication or surgery (including respiratory/cardiac diseases, uncontrolled hypertension, uncontrolled diabetes, neurological diseases, serious psychiatric disorder & blood disorders); History of allergic diseases or reactions to any drug/vaccine.

**Intervention groups**
Participants in the 12-17 years age group will receive two intramuscular doses of 10µg/200µl vaccine strengths on days 0 and 21, followed by an intranasal dose on day 51. Participants in the 5-11 years age group will receive half the dose of 12-17 years old's with the same administration schedule.

**Main outcome variables**
Primary outcomes: abnormal vital signs & anaphylactic reactions following vaccination: Local & Systemic adverse events within the first week post vaccination; abnormal lab findings within one week of vaccination; Neutralizing antibody activity VNT on days 0, 35, 90, and 180. Secondary outcomes: SAEs, SUSARs, MAAEs, up to 6 months after the second vaccine dose; Serum ELISA IgG level for SARS CoV- 2 antigens S1, RBD and cell-mediated immunity on days 0, 35, 90, and 180.

## General information

**Reason for update**
change in participant age range

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20201214049709N5**
Registration date: **2022-02-09, 1400/11/20**
Registration timing: **prospective**

Last update: **2022-06-20, 1401/03/30**
Update count: **1**

**Registration date**
2022-02-09, 1400/11/20

**Registrant information**

**Name**
Ali Eshaghi

**Name of organization / entity**
Razi Vaccine and Serum Research Institute

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-06-25, 1401/04/04

**Expected recruitment end date**
2022-10-23, 1401/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Safety and Immunogenicity of Razi Cov-2 recombinant Spike protein vaccine (RAZI Cov Pars) in healthy children and adolescents aged 5-17 years; single group, open label study

**Public title**

Safety and Immunogenicity of Razi Cov-2 recombinant Spike protein vaccine (RAZI Cov Pars) in healthy children and adolescents aged 5-17 years

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Participants legal guardian should be able to read and write Age between 5-17 years Having good health based on clinical and laboratory criteria Negative RT-PCR test for COVID-19 Signed the informed consent form Not pregnant Negative beta HCG pregnancy test on screening and vaccination day Use of at least one effective method of contraception (condoms, oral contraceptive pills, intrauterine device, Norplant capsule) and willing to continue using it in female couples

**Exclusion criteria:**

Any ongoing, symptomatic acute or chronic illness requiring continuous medical or surgical care on the day of vaccination Breastfeeding Received any Covid Vaccine Received any vaccine during the 14-days period prior to the screening day Received blood and/or any blood products and/or immunoglobulins within three months preceding the screening day History of long-term use of immunosuppressive medication (defined as more than 14 consecutive days) in the last 6 months leading up to screening day Long-term use (defined as more than 14 consecutive days) of systemic corticosteroids within the past 6 months leading up to screening day History of severe allergic diseases (such as Dyspnea, angioedema, anaphylactic reactions, urticaria and eczema) History of allergy to any drug or vaccine (defined as any clinical signs or symptom of itching at the injection site, urticaria in the body after injection, excessive redness at the injection site) History of immunological disorder (congenital or acquired) History of chemotherapy in the last 5 years History of cancer in the last 5 years History of acute and serious psychiatric illnesses History of blood disorders (dyscrasia, coagulopathy, platelet deficiency or disorder, deficiency of blood factors) Severe acute or chronic renal or hepatic failure based on laboratory parameters Suffering from chronic obstructive pulmonary disease such as asthma, or severe renal/hepatic diseases requiring continuous treatment by a specialist Uncontrolled hypertension Uncontrolled Diabetes History of chronic neurological diseases (including seizures and epilepsy) Any history of substance or alcohol abuse Grade 1 or higher abnormal laboratory (hematology or biochemistry) tests based on toxicity score on the screening day History of confirmed COVID-19 diseases during the 6-months period before the screening day (positive PCR test or clinical diagnosis) Acute febrile illness at the time of vaccination History of allergy to acetaminophen Receiving prophylactic drug against tuberculosis History of faint when see blood Splenectomy for any reason Any close contact with a confirmed COVID-19 case within two weeks before the first dose of vaccine Congenital disorders, developmental disorders, severe malnutrition or genetic diseases Participating in any clinical trials (research) other than this study

**Age**

From **5 years** old to **17 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **420**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**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**

۸۱۴۵۵۶۱۸

**Approval date**

2022-02-06, 1400/11/17

**Ethics committee reference number**

IR.NREC.1400.019

### 2

**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**

2022-06-08, 1401/03/18

**Ethics committee reference number**

IR.NREC.1401.001

## 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**

Abnormal vital signs and anaphylactic reactions immediately after vaccination: Number and percentages of participants who develop abnormal vital signs within half an hour of receiving the vaccine at each doses will be recorded. Abnormal vital signs include temperature, respiratory rate, heart rate, systolic and diastolic blood pressure before and after vaccination. 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 after each vaccination.

**Timepoint**

Before vaccination and 30 minutes after vaccination at each dose

**Method of measurement**

Temperature is measured using a digital thermometer. Blood pressure will be measured using a digital sphygmomanometer

### 2

**Description**

Local adverse reactions: The number and percentage of local adverse reactions within the first week post-vaccination (including pain, tenderness, erythema/redness, swelling and stiffness, itching)

**Timepoint**

The first seven days after 1st and 2nd vaccine dose (Days 0-7 and 21-28)

**Method of measurement**

The required information will be collected using the application installed on the mobile phones of the volunteer or their legal guardian. Volunteer will be contacted if they do not complete the relevant forms on their application.

### 3

**Description**

Systemic adverse event: The number and percentage of systemic adverse event within the first week post-vaccination (including nausea and vomiting, diarrhea, headache, fatigue, muscle pain)

**Timepoint**

The first seven days after each vaccine dose (Days 0-7, 21-28, 51-58)

**Method of measurement**

The required information will be collected using the application installed on the mobile phones of the volunteer or their legal guardian. Volunteer will be contacted if they do not complete the relevant forms on their application.

### 4

**Description**

Abnormal laboratory findings: The number and percentage of people who show abnormal laboratory findings one week after vaccination (Based on toxicity scores), including biochemistry, hematology, and urine tests. These tests include: Hemoglobin, WBC, Lymphocytes, Neutrophils, Eosinophils, Platelets ESR, CRP, Sodium, Potassium, BUN, Creatinine, Alkaline phosphatase, ALT, AST, and U/A, Urine protein, Urine glucose, Urine RBC

**Timepoint**

Seven days after each vaccine dose (Days 7, 28, 58)

**Method of measurement**

Each test will be performed using the appropriate kit.

### 5

**Description**

Measurement of neutralizing antibody titers to assess humoral immunity

**Timepoint**

Neutralizing antibody titers will be assessed on days 0, 35, 90 and 180 and comparison will be made between day 0 and other time points.

**Method of measurement**

Conventional Virus Neutralization Test (cVNT)

## Secondary outcomes

### 1

**Description**

Severe Adverse event (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSAR ) and Medically Attended Adverse Events (MAAEs)

**Timepoint**
Weekly until sixth month after second vaccine dose
**Method of measurement**
The required information will be collected using a weekly questionnaire delivered through the installed application on the volunteer mobile phone or their legal guardian. Volunteer will be contacted if they do not complete the relevant forms on their application.

**2**

**Description**
Measurement of serum levels of specific IgG antibodies against S1 and RBD components of SARS-CoV-2 spike protein antigen (s)
**Timepoint**
Measurement will be done on days zero, 35, 90 and 180 and comparison will be made between day 0 and other time points.
**Method of measurement**
Will be measured using ELISA method

**3**

**Description**
Evaluation of cell-mediated immunity by counting CD3, CD4 and CD8 cells number. IFN-γ, TNF-α, and interleukin 2, 4, 6, and 17 will also be measured following the stimulation of peripheral blood mono nuclear cells by covid 19 s antigen. Evaluation of cell mediated immunity will be performed only in 10% of participants.
**Timepoint**
Cell mediated immunity will be assessed on days 0, 35, 90 and 180 and comparison will be made between day 0 and other time points.
**Method of measurement**
Immunologic lab tests

## Intervention groups

**1**

**Description**
Intervention group: Participants in the 12-17 years age group will receive two intramuscular doses of 10µg/200µl vaccine strengths on days 0 and 21, followed by an intranasal dose on day 51. Participants in the 5-11 years age group will receive half the dose of 12-17 years old's with the same administration schedule.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Razi Vaccine and Serum Research Institute
**Full name of responsible person**
Dr Mojtaba Noofeli
**Street address**
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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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**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**
Industry

## 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

**Street address**
Hesarak - Shahid Beheshti street- Karaj

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## Person responsible for scientific inquiries

**Contact**

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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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Corner of Mansouri, Niayesh, Satarkhan Av, Tehran

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+98 21 6435 1000

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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**
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**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Public Health/Community Medicine

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Beheshti Ave, Hesarak, Karaj, Alborz Province

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**Postal code**
3197619751

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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**
De-identified 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 available after consideration and approval by the relevant authorities from Razi Vaccine and Serum Research Institute.

**Comments**