# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Jun 2026

## Immunogenicity and safety evaluation of Pastocovac Plus as the booster dose in Iranian adults aged from 18 to 80 who received two doses of Sinopharm and Astrazeneca

### Protocol summary

**Study aim**
Immunogenicity and safety evaluation of PastoCovac Plus as the booster dose in Iranian adults aged from 18 to 80 who received two doses of Sinofarm and Astrazeneca

**Design**
In this study, 190 adults (18 to 80 years old) were immunized with 2 doses of Sinopharm, Astrazeneca vaccine, which are administered in parallel and non-randomly.

**Settings and conduct**
Pasteur Institute of Iran

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: People 18 to 80 years of age who have received two doses of Sinopharm or Astrazeneca vaccine and three to six months after the second dose. Inclusion criteria: Individuals with uncontrolled underlying disease and a history of receiving any type of vaccination other than Covid-19 three months prior to enrollment.

**Intervention groups**
First dose: Sinopharm, Second dose: Sinopharm, Booster: Pastocovac Plus (Iran). First dose: Astrazeneca Second dose: Astrazeneca Booster: Pastocovac Plus (Iran). First dose: Sinopharm, Second dose: Sinopharm, Booster: Sinopharm. Groups of 20 people include: First dose: Astrazeneca, second dose: Astrazeneca, third dose: Astrazeneca, First dose: Astrazeneca, second dose: Astrazeneca, third dose: Pastocovac Plus (Cuba)

**Main outcome variables**
SARS-CoV-2 Anti SPIKE IgG;

### General information

**Reason for update**
It is an observational study that was clarified in the methods.

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20131221015878N3**
Registration date: **2022-01-18, 1400/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-20, 1400/12/01**
Update count: **2**

**Registration date**
2022-01-18, 1400/10/28

**Registrant information**

**Name**
Amitis Ramezani

**Name of organization / entity**
Pasteur Institute of Iran

**Country**
Iran (Islamic Republic of)

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**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-12-12, 1400/09/21

**Expected recruitment end date**
2022-04-10, 1401/01/21

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Immunogenicity and safety evaluation of Pastocovac Plus

as the booster dose in Iranian adults aged from 18 to 80 who received two doses of Sinopharm and Astrazeneca

**Public title**
Immunogenicity and safety evaluation of Pastocovac Plus in Iranian adults who received two doses of Sinopharm and Astrazeneca

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Signed informed written consent Able to follow the vaccination schedules, visits and tests General health and controlled underlying diseases (based on the physician's recommendation) Iranian citizenship Resident in Tehran Both sexes (male and female) Aged above 18 years Receiving 2 doses of Sinopharm vaccine with 28±5 days interval Receiving 2 doses of Astrazeneca vaccine with 3 to 4 months interval All candidates whose second vaccination either Sinopharm or Astrazeneca was done 3 to 6 prior to enrollment.

**Exclusion criteria:**
Having a history of vaccination against Covid-19 with other available vaccines History of COVID-19 based on laboratory or clinical evidence after receiving the vaccine History of any vaccinations except COVID-19 within 3 months prior to enrollment Pregnant or breastfeeding women or those who intend to become pregnant up to 3 months after the booster dose injection. Having uncontrolled hypertension (cytological pressure greater than 140 or diastolic pressure greater than 90 mm Hg) History of receiving blood or blood products such as immunoglobulin in the last three months Suffering from chronic kidney disease (GFR less than 30) Suffering from chronic liver disease (liver enzymes more than 5 times normal: 150ALT≥, 100AST≥) Suffering from uncontrolled asthma (Having had an asthma attack in the last three months) History of severe allergic reaction (anaphylaxis) to the vaccine during a person's lifetime History of treatment with immunosuppressive drugs 1 month before the booster injection (including oral and inhaled steroids (does not include topical steroids), cytostatic, interferon, immunoferon, transfer factor, Biomodulin T, any type of gammaglobin, levamisole , Heberferon, thymosin or any other immunomodulatory drug (including patients taking the above drugs due to an underlying disease). Having a fever or acute illness during the 7 days before the injection or on the day of the booster injection Suffering from an unstable heart disease

**Age**
From **18 years** old to **80 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **190**
More than 1 sample in each individual
Number of samples in each individual: **2**
Blood sample before he booster dose and one month after that

**Randomization (investigator's opinion)**
N/A

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
It is an observational study; which we follow the immunological response of those who receive an accepted booster vaccine (PastoCovac Plus).

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Pasteur Institute of Iran (Research Ethics Committee)

**Street address**
No. 69, Pasteur Ave., Tehran , Iran

**City**
Tehran

**Province**
Tehran

**Postal code**
1316943551

**Approval date**
2021-12-12, 1400/09/21

**Ethics committee reference number**
IR.PII.REC.1400.076

## Health conditions studied

### 1

**Description of health condition studied**
Covid-19

**ICD-10 code**
U11

**ICD-10 code description**
Need for immunization against COVID-19

### 2

**Description of health condition studied**
Covid-19

**ICD-10 code**
U07

**ICD-10 code description**
COVID-19, virus identified & not identified

## Primary outcomes

### 1

**Description**
Increased Anti-Spike headline
**Timepoint**
At the beginning of the study (before the intervention) and one month after the intervention (receiving a booster dose)
**Method of measurement**
Antibody titer with ELISA Kit Anti-SARS-CoV-2 QuantiVac ELISA (IgG) Kit, Euroimmun co.

### 2

**Description**
Quadrupling the neutralizing antibody titer
**Timepoint**
At the beginning of the study (before the intervention) and one month after the intervention (receiving a booster dose)
**Method of measurement**
SARS-CoV-2 Neutralizing Ab Elisa kit

## Secondary outcomes

### 1

**Description**
Evaluating safety of Booster dose
**Timepoint**
During 30 mins till one month after intervention
**Method of measurement**
Visiting cases(days 0,30) and follow up cases every two weeks by phone call.

## Intervention groups

### 1

**Description**
Intervention group: Intervention group: People receiving two doses of Sinopharm as Pastocovac Plus booster.
**Category**
Prevention

### 2

**Description**
Intervention group: Intervention group: People receiving two doses of AstraZeneca as a Pastocovac Plus booster.
**Category**
Prevention

### 3

**Description**
Intervention group: People receiving two doses of Sinopharm as a Sinopharm booster.
**Category**
Prevention

### 4

**Description**
Control group: People receiving two doses of AstraZeneca as AstraZeneca booster.
**Category**
Prevention

### 5

**Description**
Control group: People receiving two doses of AstraZeneca as a Pastocovac Plus (Cuba) booster.
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Vaccination Department of Pasteur Institute of Iran
**Full name of responsible person**
Dr. Sarah Dahmardeh
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## Sponsors / Funding sources

### 1

**Sponsor**
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Pasture Institute of Iran
**Full name of responsible person**
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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**
Pasture Institute of Iran
**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**
Pasture Institute of Iran
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Sarah Dahmardeh
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General Practitioner
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
We are preparing our data-sharing plan.
**When the data will become available and for how long**
We are preparing our data-sharing plan.
**To whom data/document is available**
We are preparing our data-sharing plan.
**Under which criteria data/document could be used**
We are preparing our data-sharing plan.

**From where data/document is obtainable**

We are preparing our data-sharing plan.

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

We are preparing our data-sharing plan.

**Comments**