

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 Sinopharm 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)

Phone

+98 21 6696 8852

Email address

amitiramezani@hotmail.com

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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No. 69, Pasteur Ave., Tehran , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pasture Institute of Iran

Full name of responsible person

Dr.Alireza Biglari

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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

Full name of responsible person

Sarah Dahmardeh

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Pasture Institute of Iran

Full name of responsible person

Amitis Ramezani

Position

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

Pasture Institute of Iran

Full name of responsible person

Anahita Bavand

Position

Laboratory Medicine

Latest degree

Master

Other areas of specialty/work

Laboratory Medicine

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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