Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone
+98 21 6696 8852

Email address
amitisramezani@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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Full name of responsible person
Sarah Dahmardeh
Position
General Practitioner
Latest degree
Medical doctor
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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