Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Immunogenicity and safety of pastocovac vaccine as a booster dose in comparison with sinopharm and pastocovac Plus boosters in Iranian adults aged 18 to 80 who received 2 doses of Sinopharm vaccine: a parallel group clinical trial

Protocol summary

Study aim
Evaluation of immunogenicity and safety of pastocovac vaccine as a booster dose in comparison with sinopharm and pastocovac Plus boosters among Iranian adults aged from 18 to 80 who received 2 doses of Sinopharm vaccine

Design
Healthy or with controlled diseases, 18-80 years. Three types of boosters will be compared: Sinofarm (75 people), Pasteucovac (75 people), and Pasteucovac Plus (75 people). This is a phase 2 non-randomized open-label parallel-group trial.

Settings and conduct
Location: Pasteur Institute of Iran. Candidates choose the booster type. Blood samples are taken on days 0, 21,60, 90, and 180 (immunogenicity). Side effects: half-hour after injection, and on days 7, 21, 60, 90, and 180.

Participants/Inclusion and exclusion criteria
Inclusion: 18-80 years who have received two doses of Sinopharm 3-6 months before enrolment. Non-inclusion: Unstable underlying disease, receipt of other Covid-19 vaccines, Covid-19 infection after Sinopharm vaccination.

Intervention groups
Intervention: 1 dose of Pastocovac (Produced by the Pasteur Institute of Iran), 3-6 months after receiving 2 doses of Sinopharm. 0.5 ml, containing 25 micrograms RBD-TT, IM. Control 1: 1 dose of Pastocovac-Plus (Produced by the Pasteur Institute of Iran), 3-6 months after receiving 2 doses of Sinopharm. 0.5 ml, containing 50 micrograms RBD-d, IM. Control 2: 1 dose of Sinopharm (produced by the Beijing Institute of Biological Products), 3-6 months after receiving 2 doses of Sinopharm. 0.5 ml, containing 6.5 units of inactivated virus, IM.

Main outcome variables
SARS-CoV-2 Anti SPIKE IgG; SARS-CoV-2 Anti RBD IgG; Virus Neutralizing Test

General information

Reason for update
Updating protocol according to first DSMB committee meeting

Acronym

IRCT registration information
IRCT registration number: **IRCT20131221015878N4**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-21, 1401/03/31**
Update count: **2**

Registration date
2022-02-26, 1400/12/07

Registrant information

Name
Amitis Ramezani

Name of organization / entity
Pasteur Institute of Iran

Country
Iran (Islamic Republic of)

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+98 21 6696 8852

Email address
amitisramezani@hotmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-26, 1400/12/07

Expected recruitment end date

2022-09-29, 1401/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Immunogenicity and safety of pastocovac vaccine as a booster dose in comparison with sinopharm and pastocovac Plus boosters in Iranian adults aged 18 to 80 who received 2 doses of Sinopharm vaccine: a parallel group clinical trial

Public title

Immunogenicity and safety of pastocovac vaccine as a booster dose in recipients of 2 doses of Sinopharm vaccine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Signed written informed consent Able to follow the vaccination schedules, visits and tests General health or having controlled underlying diseases (based on the physician's diagnosis) Iranian citizenship Residents of Tehran Both sexes (male and female) Aged 18-80 years Receiving the initial 2 doses of Sinopharm within a 28±5 days interval Completion of the 2-dose Sinopharm vaccination course within 3-6 months prior enrollment.

Exclusion criteria:

Having a history of vaccination against Covid-19 with other vaccines (in addition to 2 doses of Sinopharm) History of COVID-19 based on laboratory or clinical evidence after receiving 2 doses of Sinopharm 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 Lifetime history of severe allergic reactions (anaphylaxis) to the vaccine Coagulation disorders that contraindicate with intramuscular injection 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: **225**

More than 1 sample in each individual

Number of samples in each individual: **0**

Sample of Zero,21,60,90,180

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

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

2022-02-06, 1400/11/17

Ethics committee reference number

IR.NREC.1400.020

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 21,60,90,180 days 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
Increased Anti RBD headline
Timepoint
At the beginning of the study (before the intervention) and 21,60,90,180 days after the intervention (receiving a booster dose)
Method of measurement
Quanti-SARS-CoV-Anti-RBD ELISA (IgG) Kit, Pishtaz co.

3

Description
Increased cVNT headline
Timepoint
At the beginning of the study (before the intervention) and 21,60,90,180 days after the intervention (receiving a booster dose)
Method of measurement
SARS-CoV-2 Neutralizing Ab Elisa kit

Secondary outcomes

1

Description
Vaccine safety assessment
Timepoint
At the beginning of the study (before the intervention) and 7,21,60,90,180 days after the intervention (receiving a booster dose)
Method of measurement
Compilation form, clinical examination and telephone follow-up

Intervention groups

1

Description
Intervention group: Injection of 1 dose of Pastocovac vaccine as a booster dose, 3-6 months after receiving 2 doses of Sinopharm vaccine. The Pastocovac vaccine, produced by the Pasteur Institute of Iran, is injected intramuscularly into the deltoid muscle (0.5 ml, containing 25 micrograms of RBD conjugated with tetanus).
Category
Prevention

2

Description
Control group 1: injection of 1 dose of Pastocovac-Plus vaccine as a booster dose, 3-6 months after receiving 2 doses of Sinopharm vaccine. Pastocovac vaccine, produced by the Pasteur Institute of Iran, is injected intramuscularly into the deltoid muscle (0.5 ml, containing 50 micrograms of RBD dimer).
Category
Prevention

3

Description
Control group 2: injection of 1 dose of Sinopharm vaccine as a booster dose, 3-6 months after receiving 2 doses of Sinopharm vaccine. The Sinopharm vaccine, produced by the Beijing Institute of Biological Products, is injected intramuscularly into the deltoid muscle (containing 6.5 units of inactivated virus).
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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biglari63@hotmail.com
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
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Professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available