

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Aug 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: Sinopharm (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)

Phone

+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	Target sample size: 225
Actual recruitment start date	More than 1 sample in each individual
empty	Number of samples in each individual: 0
Actual recruitment end date	Sample of Zero,21,60,90,180
empty	Randomization (investigator's opinion)
Trial completion date	N/A
empty	Randomization description
Scientific title	Blinding (investigator's opinion)
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	Not blinded
Public title	Blinding description
Immunogenicity and safety of pastocovac vaccine as a booster dose in recipients of 2 doses of Sinopharm vaccine	Placebo
Purpose	Not used
Prevention	Assignment
Inclusion/Exclusion criteria	Parallel
Inclusion criteria:	Other design features
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.	Secondary Ids
Exclusion criteria:	empty
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	Ethics committees
Age	1
From 18 years old to 80 years old	Ethics committee
Gender	Name of ethics committee
Both	Pasteur Institute of Iran (Research Ethics Committee)
Phase	Street address
N/A	No. 69, Pasteur Ave., Tehran , Iran
Groups that have been masked	City
No information	Tehran
Sample size	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

Street address

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

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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
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Full name of responsible person
Amitis Ramezani

Position
Professor

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Specialist

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Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Anahita Bavand

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Laboratory Medicine

Latest degree
Master

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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