

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Aug 2026

Evaluation of SARS-CoV-2 Vaccine (Pastocovac) effectiveness and serologic response in Patients Receiving Hematopoietic Autologous Stem Cell Transplantation compared to control group: A clinical trial

Protocol summary

Study aim

Evaluation of the immunologic effects of COVID-19 vaccination following autologous stem cell transplantation

Design

A phase 2 controlled clinical trial on 62 transplanted patients and 62 healthy people enrolled between 01/1401 and 11/1401 and followed for one year.

Settings and conduct

The study would be conducted at the Hematology-Oncology and Stem Cell Transplantation Research Center of Tehran University. All subjects will receive two doses of pastocovac and a booster dose at four weeks (± 7 days) intervals starting from 3 months post-transplant. The efficacy of post- HSCT vaccination will be assessed through serologic responses by measurement of SARS-CoV-2 specific IgG (anti-S1) before the first vaccine, before the second vaccine, four weeks after the second vaccine, and six months after the first vaccine.

Participants/Inclusion and exclusion criteria

All consecutive adult patients more than 18 years old who underwent autologous SCT and agree to receive post-transplant COVID-19 vaccines, provided they do not receive Rituximab for the past six months.

Intervention groups

All patients who underwent autologous SCT and have inclusion criteria will be enrolled and will receive the first dose of pastocovac from 3 months post-transplant. The second dose will receive at four weeks (± 7 days) interval of the first dose and the booster will receive at four weeks (± 7 days) interval of the second dose. The serologic responses will be assessed by measurement of SARS-CoV-2 specific IgG (anti-S1) before the first vaccine, before the second vaccine, four weeks after the second vaccine, and six months after the first vaccine.

Main outcome variables

SARS-CoV-2 vaccine immunologic response by

measuring SARS-CoV-2 IgG (anti-S1) titer at four weeks post second COVID-19 vaccine than pre vaccination titer in autologous HSCT recipients compared to a healthy population

General information

Reason for update

Adding a healthy control group to compare the serological response following vaccine between transplanted recipients with the healthy group

Acronym

ESVAHSCT

IRCT registration information

IRCT registration number: **IRCT20140818018842N23**

Registration date: **2022-04-03, 1401/01/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-21, 1401/05/30**

Update count: **1**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation, Tehran University of Medic

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2023-02-03, 1401/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of SARS-CoV-2 Vaccine (Pastocovac) effectiveness and serologic response in Patients Receiving Hematopoietic Autologous Stem Cell Transplantation compared to control group: A clinical trial

Public title

Evaluation of the Pastocovac (COVID-19 vaccine) efficacy following autologous stem cell transplantation

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**All autologous stem cell transplantation Age ≥ 18 **Exclusion criteria:**

patients who received Rituximab during the past six months. Patients who do not consent to vaccination after transplantation

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

2

Groups that have been masked

No information

Sample sizeTarget sample size: **124**

More than 1 sample in each individual

Number of samples in each individual: **4**

Sampling for SARS-CoV-2 specific IgG (anti-S1) titers in post autologous transplantation, as well in a healthy population, as follows: before the first vaccine, one week before the second vaccine, four weeks after the second vaccine, and six months after the first vaccine.

Randomization (investigator's opinion)

Not randomized

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**

Ethic committee of Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran Univer

Street address

Kargar shomali Ave., Shariati hospital

City

Tehran

Province

Tehran

Postal code

14114

Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1400.035

Health conditions studied**1****Description of health condition studied**

Autologous stem cell transplantation

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

SARS-CoV-2 vaccine efficacy

ICD-10 code**ICD-10 code description**

SARS-CoV-2 vaccine effectiveness

Primary outcomes**1****Description**

SARS-CoV-2 specific IgG (anti-S1) titer

Timepoint

Four weeks after the second vaccine

Method of measurement

Enzyme-linked immunosorbent assay

Secondary outcomes**1****Description**

SARS-CoV-2 specific IgG (anti-S1) titer

Timepoint

Four weeks after the first vaccine

Method of measurement

2**Description**

Cumulative incidence of COVID-19

Timepoint

12 months following bone marrow transplantation

Method of measurement

RT-PCR test

Intervention groups1**Description**

Intervention group: All patients who underwent autologous SCT and have inclusion criteria will be enrolled and will receive the first dose of pastocovac from 3 months post-transplant. The second dose will receive at four weeks (± 7 days) interval of the first dose and the booster will receive at four weeks (± 7 days) interval of the second dose. The serologic responses will be assessed by measurement of SARS-CoV-2 specific IgG (anti-S1) before the first vaccine, before the second vaccine, four weeks after the second vaccine, and six months after the first vaccine.

Category

Prevention

2**Description**

Control group: The control group includes healthy people who have received two doses of Pastococcal vaccine with the same formula and dose as the intervention group, and the antibody titer is measured before and after each dose of the vaccine

Category

Prevention

Recruitment centers1**Recruitment center****Name of recruitment center**

Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran University of Medical Sci

Full name of responsible person

Maryam Barkhordar

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North Kargar Ave.

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Email**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

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

2**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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Leyla Sharifi Aliabadi

Position
Research Assistant

Latest degree
Bachelor

Other areas of specialty/work
Epidemiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available