

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Aug 2026

Evaluation of safety and immunogenicity of the SARS-CoV-2 recombinant spike RBD protein vaccine in Patients Receiving Allogeneic Hematopoietic Stem Cell Transplantation; A phase 2 clinical trial

Protocol summary

Study aim

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

Design

A single-arm, phase 2 clinical study to assess the efficacy of the COVID-19 vaccine following allogeneic HSCT on 40 consecutive patients enrolled between 01/2022 and 09/2022 and followed for one year

Settings and conduct

All patients who underwent allo-HSCT at the Stem Cell Transplantation Research Center of Tehran University are enrolled from 3 to 12 months after Allo-HSCT and are vaccinated with the three doses of Pastucovac. SARS-CoV-2 specific IgG (anti-S1) and immune subsets reconstitution are measured to assess the immune response.

Participants/Inclusion and exclusion criteria

All recipients of Allo-HSCT who meet the criteria, including; "age $\geq$ 18 years, successfully engraftment with full donor chimerism, absence of grade 3,4 acute GvHD or severe extensive chronic GvHD, no receive more than 0.5 mg/kg prednisolone, and no positive RT-PCR test for COVID-19 during the last three months" are enrolled to study from 3 to 12 months after Allo-HSCT.

Intervention groups

All patients who underwent allo-HSCT and have inclusion criteria are enrolled from 3 to 12 months after Allo-HSCT and will be vaccinated with the first two doses of Pastucovac at a 4-week ($\pm$ 7 days) interval and a third additional dose with an 8-week ($\pm$ 7 days) interval from the second dose. The blood samples are collected before the first vaccine and three weeks ($\pm$ one week) after each dose of vaccine to assess serologic response.

Main outcome variables

To assess the serologic response, by measurement of SARS-CoV-2 binding antibody titer 3-week ($\pm$ 7 days) after the second dose of vaccine; To describe vaccine-

related adverse reactions until 14 days after administration of each vaccine dose.

General information

Reason for update

Adding Pasture Institute of Iran as one of the study's sponsors

Acronym

ESVIRHSCT

IRCT registration information

IRCT registration number: **IRCT20140818018842N22**

Registration date: **2022-01-12, 1400/10/22**

Registration timing: **prospective**

Last update: **2022-05-31, 1401/03/10**

Update count: **2**

Registration date

2022-01-12, 1400/10/22

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 3691

Email address

ctu@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and immunogenicity of the SARS-CoV-2 recombinant spike RBD protein vaccine in Patients Receiving Allogeneic Hematopoietic Stem Cell Transplantation; A phase 2 clinical trial

Public title

Evaluation of the COVID-19 vaccine efficacy following allogeneic stem cell transplantation

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Allogeneic stem cell transplantation successfully engraftment with full donor chimerism Age ≥ 18 between 3 to 12 months after Allo-HSCT

Exclusion criteria:

grade 3,4 acute GvHD or severe extensive chronic GvHD Patients who do not consent to vaccination after transplantation receive more than 0.5 mg/kg/day prednisolone positive RT-PCR test for COVID-19 during the last three months

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

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **40**

More than 1 sample in each individual

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

Sampling for SARS-CoV-2 specific IgG (anti-S1) titers will be performed for recipients of allo-HSCT before the conditioning regimen, prior to the first vaccine, and three weeks ($\pm$ one week) after each dose of vaccine.

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

2021-10-29, 1400/08/07

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1400.021

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

Allogeneic stem cells transplantation

ICD-10 code

Z94.84

ICD-10 code description

Stem cells transplant status

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

2**Description**

B lymphocyte count

Timepoint

Three months after allogeneic transplantation

Method of measurement

multicolor flow cytometry

3**Description**

NK cell count

Timepoint

Three months after allogeneic transplantation

Method of measurement

multicolor flow cytometry

4

Description

T cell count

Timepoint

Three months after allogeneic transplantation

Method of measurement

multicolor flow cytometry

5

Description

Cumulative incidence of COVID-19

Timepoint

12 months following bone marrow transplantation

Method of measurement

RT-PCR test

6

Description

Acute graft versus host disease

Timepoint

100 days following bone marrow transplantation

Method of measurement

Physical exam, biopsy, lab test

7

Description

Overall survival

Timepoint

12 months following bone marrow transplantation

Method of measurement

electronic data bank

Secondary outcomes

1

Description

Overall survival

Timepoint

One-year post transplantation

Method of measurement

Time

2

Description

Acute Graft versus Host Disease

Timepoint

100 days post-transplantation

Method of measurement

physical exam, lab test, and biopsy

3

Description

Relapse

Timepoint

One-year post-transplantation

Method of measurement

bone marrow aspiration and biopsy

Intervention groups

1

Description

All consecutive adult patients who are candidates for Allo-HSCT at HORCSCT are recruited. They sign an informed consent to administer the Pastocovac vaccine and take blood samples. All patients who meet the inclusion criteria are enrolled to study from 3 to 12 months after Allo-HSCT and will be vaccinated with the first two doses of Pastucovac at a 4-week (± 7 days) interval and a third additional dose with an 8-week (± 7 days) interval from the second dose. Peripheral blood samples are collected before conditioning and before the first dose of vaccine to test particular lymphocyte subpopulations and SARS-CoV-2 IgG titers. The blood samples are also collected three weeks ($\pm$ one week) after each dose of vaccine to assess serologic response by SARS-CoV-2 IgG titer.

Category

Treatment - Drugs

Recruitment centers

1

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

Street address

Shariati hospital, North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1417713135

Phone

+98 21 8800 4140

Email

barkhordarm.n@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Barkhordar

Street address

Shariati hospital, North Kargar Ave.

City

Tehran

Province
Tehran

Postal code
1417713135

Phone
+98 21 8800 4140

Email
mbarkhordar@sina.tums.ac.ir

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
Rahim sorouri

Street address
Pasteur Institute of Iran (IPI), No. 69, Pasteur Ave,
Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1316943551

Phone
+98 21 6695 4321

Email
r.sorouri@pasteur.ac.ir

Web page address
<https://en.pasteur.ac.ir/>

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
30

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
Tehran University of Medical Sciences

Full name of responsible person
Leyla Sharifi Aliabadi

Position
Research Assistant

Latest degree
Master

Other areas of specialty/work
Epidemiology

Street address
Shariati Hospital, North Kargar Ave.

City
Tehran

Province
Tehran

Postal code
1417713135

Phone
00982288004140

Email
ctu@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Maryam Barkhordar

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

Street address
Shariati Hospital, North Kargar Ave.

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 2635

Email
mbarkhordar@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Leyla Sharifi Aliabadi

Position

Research Assistant

Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

Shariati Hospital, North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8800 4140

Email

ctu@sina.tums.ac.ir

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