Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 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 ≥ 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 (±7 days) interval and a third additional dose with an 8-week (±7 days) interval from the second dose. The blood samples are collected before the first vaccine and three weeks (± 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 (±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

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Iran (Islamic Republic of)

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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
Age
From **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 (± 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 (± 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Rahim sorouri
Street address
Pasteur Institute of Iran (IPI),No. 69,Pasteur Ave, Tehran, Iran.
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Web page address
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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
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
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Leyla Sharifi Aliabadi
Position
Research Assistant
Latest degree
Master
Other areas of specialty/work
Epidemiology
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Person responsible for updating data

Contact
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Leyla Sharifi Aliabadi

Position

Research Assistant

Latest degree

Master

Other areas of specialty/work

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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