Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of SARS-CoV-۲ 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-۱۹ 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

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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-۲ 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
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: **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

Enzyme-linked immunosorbent assay

2

Description
Cumulative incidence of COVID-19
Timepoint
12 months following bone marrow transplantation
Method of measurement
RT-PCR test

Intervention groups

1

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 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
Tehran University of Medical Sciences
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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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1316943551
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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
Industry

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
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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