Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the serological response to the heterologous versus homologous booster vaccinationin in patients receiving autologous hematopoietic stem cell transplantation

Protocol summary

Study aim

Comparing safety and serological response following homologous vs. heterologous COVID-19 booster vaccine in patients receiving autologous hematopoietic stem cell transplants(AHSCT)

Design

This is a phase 2-3 double-blind, randomized controlled clinical trial to compare the serological response of the homologous COVID-19 vaccine versus the heterologous booster dose in 90 adult patients receiving AHSCT. For randomization, a balanced block randomization list was generated using the research institute's Web-based software, after entering the sample size and number of each block.

Settings and conduct

Eligible adult patients receiving AHSCT in a research institute for oncology, hematology, and cell therapy, will be invited four weeks (±7 days) after the 2nd dose. After obtaining the written informed consent, COVID-19 rapid test and antibody titer test will be performed, afterward, the national code enter into the system, and the vaccine code will be announced. The vaccine will be injected. Antibody titer and Side effects are evaluated four weeks (±7 days) after the vaccination.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age: 18-70 Time interval: 6 to 12 months after AHSCT Receiving two doses of Pastocovac vaccine, Exclusion criteria: Relapse of underlying disease

Intervention groups

Group A is a homologous vaccine (Pastocovac), and group B is a heterologous vaccine (Sinopharm). In both groups, the rapid COVID-19 test will be performed, and then the blood sample will be tested to measure the COVID-19 antibody titer. The patient will randomly receive the vaccine, and after four weeks (±7 days), the patient's blood sample will test for antibody titer, and the vaccine's side effects will be recorded.

Main outcome variables

SARS-CoV-2 Anti SPIKE IgG titer three weeks (±7 days) following homologous versus heterologous booster vaccine

General information

Reason for update

Recruitment has been completed. Trial has already been completed

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N24**
Registration date: **2022-07-22, 1401/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-09, 1402/05/18**
Update count: **2**

Registration date

2022-07-22, 1401/04/31

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-22, 1401/04/31

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

2022-07-22, 1401/04/31

Actual recruitment end date

2023-01-21, 1401/11/01

Trial completion date

2023-03-21, 1402/01/01

Scientific title

Evaluation of the serological response to the heterologous versus homologous booster vaccinationin in patients receiving autologous hematopoietic stem cell transplantation

Public title

Evaluation of the serological response to booster vaccinationin in patients receiving autologous hematopoietic stem cell transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have undergone autologous hematopoietic stem cell transplantation Between 6 months and 12 months after transplantation They have received two initial doses of Pastocovac vaccine At least one month after receiving the second dose

Exclusion criteria:

Treatment with rituximab during last 6 months Relapse of underlying disease Positive rapid COVID-19 test before booster dose vaccination Patients who do not consent to vaccination

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **61**

Randomization (investigator's opinion)

Randomized

Randomization description

Assigning to the study groups is a parallel; group A is considered the intervention group of homologous vaccine (Pastocovac vaccine), and group B is the intervention group of heterologous vaccine (Sinopharm vaccine). The balanced block randomization list will be generated through the research institute's web-based software; after entering the sample size 90 and considering the block size of 4, according to this balanced block randomization list, a sequence of numbers is created, and this sequence of numbers is defined in the system. If the patients meet the criteria of the study after obtaining informed consent, their national code will be entered into the system, and the software will announce the code of each patient. Patients receive one of two vaccines randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to ethical considerations, a placebo arm will not be used. 10-dose vials of both types of vaccines are given to a person outside the research team. At pre-determined times when some patients come to inject a booster dose, each vial of 10-dose Sinopharm or Pastocococ vaccine is poured into ten insulin syringes as a single dose by the responsible person and is coded by the sequence of numbers according to a random list and considering the cold chain. The code label has already been prepared and is provided to that person. Coded vaccine syringes will be placed in a special refrigerator at a temperature of 2-4 degrees until the time of injection, which should be half an hour. Apart from the above person, all the research team members, including the Care provider, the person responsible for injecting the vaccine, the person responsible for collecting information, the analyst, and the patient, are not aware of the type of vaccine.

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

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Shariati hospital, Kargar shomali Ave

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Postal code

1411713135

Approval date

2022-07-04, 1401/04/13

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1401.005

Health conditions studied

1

Description of health condition studied

Multiple myeloma

ICD-10 code

C90

ICD-10 code description

Multiple myeloma and malignant plasma cell neoplasms

2

Description of health condition studied

Non-Hodgkin lymphoma

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

3

Description of health condition studied

Hodgkin lymphoma

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

4

Description of health condition studied

Myelodysplastic syndrome

ICD-10 code

D46

ICD-10 code description

Myelodysplastic syndromes

Primary outcomes

1

Description

SARS-CoV-2 antibody titers

Timepoint

before the start of the intervention and 4 weeks (±7 days) after the injection of the booster dose vaccine

Method of measurement

ChemoBind SARS-CoV-۲ IgG Test

Secondary outcomes

1

Description

Probable Side effect: local pain, fever, fatigue, headache and sore throat

Timepoint

One week after vaccination

Method of measurement

Vaccine side effects checklist

Intervention groups

1

Description

Intervention group 1: injection of one homologous booster dose of Pastocovac 4 weeks (±7 days) after receiving two doses of primary Pastocovac vaccine, that is injected intramuscularly 0.5 ml into the deltoid muscle

Category

Treatment - Other

2

Description

Intervention group 2: injection of one heterologous booster dose of Sinopharm 4 weeks (±7 days) after receiving two doses of primary Pastocovac vaccine, that is injected intramuscularly 0.5 ml into the deltoid muscle

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Reseach Institute for Oncology ,Hematology and Cell Therapy, Tehran University of Medical Sci

Full name of responsible person

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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

Person responsible for general inquiries

Contact

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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

Trial results

Please tick if results have been published

Yes

Summary result posting date

2023-08-09, 1402/05/18

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

2023-08-01, 1402/05/10

Abstract of published paper

Background/Purpose: Optimizing vaccine efficacy is of particular concern in patients undergoing hematopoietic stem cell transplantation (HSCT), which mainly have an inadequate immune response to primary SARS-CoV-2 vaccination. This investigation aimed to explore the potential prime-boost COVID-19 vaccination strategies following autologous (auto-) HSCT. Methods: In a randomized clinical trial, patients who had already received two primary doses of receptor-binding domain (RBD) tetanus toxoid (TT) conjugated SARS-CoV-2 vaccine during three to nine months after auto-HSCT were randomized to receive either a homologous RBD-TT conjugated or heterologous inactivated booster dose four weeks after the primary vaccination course. The primary outcome was comparing the anti-S IgG Immune status ratio (ISR) four weeks after the heterologous versus homologous booster dose. The assessment of safety and reactogenicity adverse events was considered as the secondary outcome.(IRCT Id IRCT20140818018842N24) Results: Sixty-one auto-HSCT recipients were recruited and randomly assigned to receive either homologous or heterologous booster doses four weeks after the primary vaccination course. The mean ISR was 3.40 (95% CI: 2.63- 4.16) before the booster dose with a 90.0% seropositive rate. The ISR raised to 5.12 (95% CI: 4.15- 6.08) with a 100% seropositive rate after heterologous (P= 0.0064) and to 3.42 (95% CI: 2.67- 4.17) with a 93.0% seropositivity after the homologous booster doses (P= 0.96). In addition, the heterologous group suffered more AEs following the booster dosage than the homologous group, but this difference was not statistically significant (p = 0.955). In multivariable analysis, the primeboost vaccination strategy (heterologous versus homologous), the level of ISR before the booster dose, and the length of time between auto-HSCT and booster dose were the positive predictors of serologic response to a booster dose. No serious adverse event is attributed to booster vaccination. Conclusion: In patients who were primed with two SARS-CoV-2 vaccine doses during the first year after auto-HSCT, heterologous prime-boost COVID-19 vaccination with inactivated platform resulted in considerably enhanced serologic response and non-significantly higher reactogenicity adverse events than homologous RBD-TT conjugated prime-boost COVID-19 vaccination strategy. KEYWORDS SARS-CoV-2, heterologous prime boost COVID-19 vaccination, hematopoietic stem cell transplantation, RBD subunit vaccine, inactivated vaccines, immunogenicity