Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A study to evaluate the efficacy of Atorvastatin in the prophylaxis of acute graft-versus-host disease in allogeneic hematopoietic stem cell transplantation (HSCT)

Protocol summary

Study aim

Evaluating the efficacy of Atorvastatin in the prophylaxis of acute graft-versus-host disease (Acute GVHD) in recipients of allogeneic hematopoietic stem cell transplantation (HSCT).

Design

This is a randomized, double-blind, placebo-controlled, parallel-group trial in which patients are divided into groups: A and B based on a computer-generated block randomization list. Then, patients and donors receive their medicine based on the protocol and are monitored at each follow-up visit.

Settings and conduct

Allo-HSCT candidates in Shariati hospital were divided into two groups (Atorvastatin and placebo recipients) based on a computer-generated block randomization list. Both groups receive treatment from day 14 before transplantation to day 180 after transplantation or until the incidence of severe GVHD (grade II-IV). Data are obtained by researchers in the BMT ward, post-transplant clinic, and emergency unit for hematology patients through a questionnaire in two steps: 1) before and during hospitalization in BMT wards, 2) after hospital discharge, and follow-up clinic visits.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a history of hematologic malignancies or bone marrow failure syndromes Recipient age: 18 to 60 years of age A fully HLA-matched family donor Exclusion criteria: Pregnant women or lactating mothers

Intervention groups

Allo-HSCT candidates in Shariati Hospital bone marrow transplant wards were divided into two groups: Atorvastatin (40mg/daily) and Placebo recipients. Both groups receive treatment from day 14 before transplantation to day 180 after transplantation or until the incidence of severe GVHD (grade II-IV).

Main outcome variables

Acute GVHD (skin,liver,gut): the first 100 days after transplantation Chronic GVHD: after 100 days of transplantation Mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N27**
Registration date: **2022-12-03, 1401/09/12**
Registration timing: **retrospective**

Last update: **2022-12-03, 1401/09/12**
Update count: **0**

Registration date

2022-12-03, 1401/09/12

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

2015-08-23, 1394/06/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2015-08-23, 1394/06/01

Actual recruitment end date

2019-02-20, 1397/12/01

Trial completion date

2019-08-23, 1398/06/01

Scientific title

A study to evaluate the efficacy of Atorvastatin in the prophylaxis of acute graft-versus-host disease in allogeneic hematopoietic stem cell transplantation (HSCT)

Public title

A study to evaluate the effect of Atorvastatin in GvHD

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Donor age : 18 years or above Normal liver function in donors Normal renal function in recipients KPS =>60 for donors Patients with a history of hematologic malignancies or bone marrow failure syndromes Recipient age: 18 to 60 years A fully HLA-matched family donor LVEF=>40% for recipients Normal liver function in recipients Normal renal function in donors KPS =>70 for recipients There is no no prohibition for patients who already received Atorvastatin

Exclusion criteria:

Pregnant women and lactating mothers Positive history of hypersensitivity to Atorvastatin in donors HIV-positive donors HIV-positive recipients Positive history of hypersensitivity to Atorvastatin in recipients Patients receiving ATG

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **75**

Actual sample size reached: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

According to a computer-generated block randomization list, patients are given a code, and then they are divided into groups A (Atorvastatin recipients) and B (placebo recipients). In this study, participants, caregivers, and researchers are blinded to group assignments. The results are reported by the person not involved in the study after completion of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to a computer-generated block randomization list, patients are given a code, and then they are divided into groups A (Atorvastatin recipients) and B (placebo recipients). In this study, participants, caregivers, and researchers are blinded to group assignments. The results are reported by the person not involved in the study after completion of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Ethics Committee of Tehran University of Medical Sciences, Keshavararz Blvd. ,Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2015-05-26, 1394/03/05

Ethics committee reference number

IR.TUMS.REC1394.1435

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukemia [ALL]

ICD-10 code

c91.0

ICD-10 code description

2

Description of health condition studied

Acute myeloid leukemia [AML]

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes

1

Description
Acute GVHD
Timepoint
Weekly monitoring until 100 days after transplant
Method of measurement
Clinical assessment

2

Description
Oral mucositis
Timepoint
Weekly monitoring until 100 days after transplant
Method of measurement
Clinical assessment

Secondary outcomes

1

Description
Overall survival
Timepoint
Three years after transplantation
Method of measurement
Patient follow-up

2

Description
Disease-free survival
Timepoint
Three years after transplantation (1- 2 month intervals)
Method of measurement
Clinical assessment

3

Description
Atorvastatin safety
Timepoint
Since 14 days before transplantation until 100 days after transplatation with 15-,30-,60- ,and 90-day intervals
Method of measurement
Clinical assessment as well as monitoring liver and muscle enzymes if necessary

Intervention groups

1

Description
Intervention group: In this group, Atorvastatin 40 mg (Abidi Pharmaceutical Co.) is given daily to both donor and transplant recipients from 14 days before transplantation until 180 days after transplantation (for transplant recipient) or until the incidence of side effects or severe GVHD.
Category
Treatment - Drugs

2

Description
Control group: In this group, Placebo 40 mg (Abidi Pharmaceutical Co.) is given daily to both donor and transplant recipients from 14 days before transplantation until 180 days after transplantation (for transplant recipient) or until the incidence of side effects or severe GVHD.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology, Oncology and Stem Cell Transplantation Research Center
Full name of responsible person
Mohammad Vaezi
Street address
Kargar-e-shomali Ave., Shariati Hospital
City
Tehran
Province
Tehran
Postal code
1411713131
Phone
+98 21 8490 2635
Fax
+98 21 8800 4140
Email
vaezi.mohammad@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seied Asadollah Mousavi
Street address
Kargar-e-Shomali Ave., Shariati Hospital
City
Tehran
Province
Tehran
Postal code
1411713131
Phone
+98 21 8490 2635
Fax
+98 21 8800 4140
Email

ctu@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Hematology, Oncology and Stem Cell Transplantation Research Center, 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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parsa Rostami

Position

Hematology- Medical Oncology Fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Kargar-e-shomali Ave., Shariati Hospital

City

Tehran

Province

Tehran

Postal code

1411713131

Phone

+98 21 8490 2635

Fax

+98 21 8800 4140

Email

rostami.parsa@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Vaezi

Position

Subspecialty in Hematology and Medical Oncology

Latest degree

Subspecialist

Other areas of specialty/work

Hematology and Medical Oncology

Street address

Kargar-e-Shomali Ave., Shariati Hospital

City

Tehran

Province

Tehran

Postal code

1411713131

Phone

+98 21 8490 2635

Fax

+98 21 8800 4140

Email

vaezi.mohammad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Leyla Sharifi Aliabadi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Kargar-e-Shomali Ave., Shariati Hospital

City

Tehran

Province

Tehran

Postal code

1411713131

Phone

+98 21 8490 2635

Fax

+98 21 8800 4140

Email

l-sharifi@tums.ac.ir

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