

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Evaluation of progenitor cell mobilizing effect of atorvastatin in autologous hematopoietic stem cell transplantation

#### Protocol summary

##### Summary

1. Objectives Evaluation of hematopoietic progenitor cell mobilizing effect of atorvastatin in autologous hematopoietic stem cell transplantation 2. Design Double-blind randomized placebo-controlled trial 3. Setting and conduct Forty four hospitalized patients admitted for autologous stem cell transplantation will be allocated to either intervention or control groups using permuted block randomization model 4. Participants All patients candidates for autologous stem cell transplantation with primary diagnoses of Hodgkin's lymphoma, non-Hodgkin's lymphoma or multiple myeloma; who age at least 18 years old; and endorse the inform consent will be recruited. Patients who are taking any statin drug (lovastatin, simvastatin, atorvastatin, fluvastatin, rozuvastatin) at the time of enrollment; or develop suspected drug related toxicity during treatment will be excluded from study 5. Intervention Patients allocated to intervention group will receive atorvastatin 40 mg daily initiated at the time of hospitalization and continued to the day of cell harvest plus standard filgrastim regimen. Patients allocated to control group will receive placebo on a daily basis initiated at the time of hospitalization and continued to the day of cell harvest plus standard filgrastim regimen 6. Main outcome measures Primary outcome is the mean number of hematopoietic progenitor cells per microliter of peripheral blood before cell harvest. Secondary outcomes consist of occurrence of bleeding or infectious episodes, mean dose of filgrastim needed for stem cell mobilization before cell harvest or for engraftment after transplantation, time of leukocyte and platelet engraftments, duration of hospitalization and mortality

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014071418484N1**

Registration date: **2015-03-09, 1393/12/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-03-09, 1393/12/18

##### Registrant information

###### Name

Mehdi Mohammadi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6695 4709

###### Email address

mohammadi-m@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

##### Expected recruitment start date

2013-10-23, 1392/08/01

##### Expected recruitment end date

2014-08-22, 1393/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of progenitor cell mobilizing effect of atorvastatin in autologous hematopoietic stem cell transplantation

## Public title

Use of atorvastatin in bone marrow transplantation

## Purpose

Supportive

## Inclusion/Exclusion criteria

Major inclusion criteria: Age equals to or greater than 18; Primary diagnosis consist of Hodgkin's lymphoma, Non-Hodgkin's lymphoma or Multiple Myeloma; Patient endorsement of informed consent Major exclusion criteria: Patients taking any statin drug at the time of enrollment; Occurrence of suspected drug related toxicity during treatment

## Age

From **18 years** old to **139 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **44**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## 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

6th floor, central TUMS bldg, next to the Qods St, Keshavarz Blv

##### City

Tehran

##### Postal code

#### Approval date

2015-01-28, 1393/11/08

#### Ethics committee reference number

8911358006-135492

## Health conditions studied

### 1

#### Description of health condition studied

Follicular lymphoma

#### ICD-10 code

C82

#### ICD-10 code description

Follicular lymphoma

### 2

#### Description of health condition studied

Hodgkin lymphoma

#### ICD-10 code

C81

#### ICD-10 code description

Hodgkin lymphoma

### 3

#### Description of health condition studied

Non-follicular lymphoma

#### ICD-10 code

C83

#### ICD-10 code description

Non-follicular lymphoma

### 4

#### Description of health condition studied

Multiple myeloma and malignant plasma cell neoplasms

#### ICD-10 code

C90

#### ICD-10 code description

Multiple myeloma and malignant plasma cell neoplasms

## Primary outcomes

### 1

#### Description

Mean number of hematopoietic progenitor cells per microliter of peripheral blood

#### Timepoint

Baseline, at the time of cell harvest

#### Method of measurement

Number of cells by flowcytometry assessment

## Secondary outcomes

### 1

#### Description

Time of platelet recovery

#### Timepoint

Any time after transplantation in which platelet engraftment occurs

#### Method of measurement

Complete blood count test

### 2

#### Description

|                                    |                                                                           |
|------------------------------------|---------------------------------------------------------------------------|
| Time of polymorphonuclear recovery |                                                                           |
| <b>Timepoint</b>                   | Any time after transplantation in which polymorphonuclear recovery occurs |
| <b>Method of measurement</b>       | Complete blood count test                                                 |
| <b>3</b>                           |                                                                           |
| <b>Description</b>                 | Occurrence of bleeding episodes                                           |
| <b>Timepoint</b>                   | Any time after transplantation and before discharge                       |
| <b>Method of measurement</b>       | Occurrence or non                                                         |
| <b>4</b>                           |                                                                           |
| <b>Description</b>                 | Occurrence of infection episodes                                          |
| <b>Timepoint</b>                   | Any time after transplantation and before discharge                       |
| <b>Method of measurement</b>       | Occurrence or non                                                         |
| <b>5</b>                           |                                                                           |
| <b>Description</b>                 | Mean dose of filgrastim for stem cell mobilization                        |
| <b>Timepoint</b>                   | Before cell harvest                                                       |
| <b>Method of measurement</b>       | Sum of administered doses                                                 |
| <b>6</b>                           |                                                                           |
| <b>Description</b>                 | Mean dose of filgrastim for engraftment                                   |
| <b>Timepoint</b>                   | After transplantation until discharge                                     |
| <b>Method of measurement</b>       | Sum of administered doses                                                 |
| <b>7</b>                           |                                                                           |
| <b>Description</b>                 | Duration of hospitalization                                               |
| <b>Timepoint</b>                   | From the day of stem cell infusion until the day of discharge             |
| <b>Method of measurement</b>       | Number of days                                                            |
| <b>8</b>                           |                                                                           |
| <b>Description</b>                 | Mortality                                                                 |
| <b>Timepoint</b>                   | From the day of stem cell infusion until the day of discharge             |
| <b>Method of measurement</b>       | Occurrence or non                                                         |

## Intervention groups

### 1

#### Description

Intervention: Atorvastatin 40 mg daily PO started from the first day of hospitalization and continued until the day of cell harvest plus standard filgrastim regimen

#### Category

Treatment - Drugs

### 2

#### Description

Control: Placebo once daily PO started from the first day of hospitalization and continued until the day of cell harvest plus standard filgrastim regimen

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hematology-Oncology and Stem Cell Research Center

##### Full name of responsible person

Mohammad Vaezi, Assistant professor, Hematologist

##### Street address

Shariati Hospital, Karegar Ave.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

##### Full name of responsible person

Masud Yunesian

##### Street address

6th floor, Central TUMS Bldg, next to the Qods St, Keshavarz Blvd

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Research Center for Rational Use of Drugs  
**Full name of responsible person**  
Molouk Hadjibabaie  
**Position**  
Professor  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*