

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 2026

Effects of oral calcitriol versus placebo on hematologic and immunologic reconstitution after autologous hematopoietic stem cell transplantation: a double-blind, randomized clinical trial

Protocol summary

Summary

This double-blind, placebo-controlled, one-centered, randomized clinical trial aims to assess the effects of oral calcitriol on the short-term and long-term hematologic and immunologic reconstitution after autologous peripheral blood hematopoietic stem cell transplantation. Patients age between 16 and 65 years with Hodgkin's lymphoma, non-Hodgkin's lymphoma, or multiple myelomas candidate for autologous peripheral blood hematopoietic stem cell transplantation will be enrolled and patients with baseline serum calcium >10.5mg/dL, phosphorous >4.5mg/dL, renal or liver complications, sensitivity to calcitriol, or disability for oral intake will be excluded. In all, 60 patients will be equally randomized between the calcitriol and placebo groups. Baseline serum levels of 25-OH-D and 1,25-(OH)₂-D will be measured before the conditioning regimen. Oral calcitriol 0.25mcg or placebo pearls will be administered three times daily after the conditioning regimen up to day +30 after the transplantation. Complete blood count and differential test will be performed daily to evaluate the counts of absolute neutrophils, platelets, absolute lymphocytes, absolute monocytes, and hemoglobin. Serum level of 1,25-(OH)₂-D will be also measured on days +15 and +30 after the transplantation. After a 6-month median, long-term engraftment and recovery of leukocytes, platelets, and hemoglobin as well as the disease-free survival will be assessed. Primary outcomes include the time to engraftment of absolute neutrophils, platelets, and absolute lymphocytes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120816837N2**

Registration date: **2016-05-26, 1395/03/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-26, 1395/03/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Center of the Hematology and Oncology and Stem Cell Transplantation, Shariati Hospital, Tehran, Iran.

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral calcitriol versus placebo on hematologic and immunologic reconstitution after autologous hematopoietic stem cell transplantation: a double-blind, randomized clinical trial

Public title

Effects of calcitriol on the complications of hematopoietic stem cell transplantation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 16 and 65 years; cases of Hodgkin's lymphoma, non-Hodgkin's lymphoma, or multiple myelomas; candidates for autologous peripheral blood hematopoietic stem cell transplantation. Exclusion criteria: baseline serum calcium >10.5mg/dL; baseline serum phosphorous >4.5mg/dL; history of renal stones in the past 5 years; baseline serum creatinine >1.3mg/dL; alkaline phosphatase x4 the upper limit of normal or higher; alanine transaminase >60U/L; total bilirubin >2mg/dL; sensitivity to calcitriol; disability for oral intake.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Medical Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, 16 Azar Ave, Enqelab Ave, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-12-08, 1394/09/17

Ethics committee reference number

IR.TUMS.REC.1394.1368

Health conditions studied

1

Description of health condition studied

Hodgkin's lymphoma

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

2

Description of health condition studied

Non-Hodgkin's lymphoma

ICD-10 code

C82, C83,

ICD-10 code description

Follicular lymphoma, Non-follicular lymphoma, Mature T/NK-cell lymphomas, Other and unspecified types of non-Hodgkin lymphoma

3

Description of health condition studied

Multiple myelomas

ICD-10 code

C90

ICD-10 code description

Multiple myeloma and malignant plasma cell neoplasms

Primary outcomes

1

Description

Time to absolute neutrophil engraftment

Timepoint

Every day after transplantation up to the day of absolute neutrophil engraftment

Method of measurement

Complete Blood Count and Differential Test

2

Description

Time to platelet engraftment

Timepoint

Every day after transplantation up to the day of platelet engraftment

Method of measurement

Complete Blood Count Test

3

Description

Time to absolute lymphocyte recovery

Timepoint

Every day after transplantation up to the day of absolute lymphocyte recovery

Method of measurement

Complete Blood Count and Differential Test

Secondary outcomes**1****Description**

Absolute neutrophil count on day +15 after the transplantation

Timepoint

Day +15 after the transplantation

Method of measurement

Complete Blood Count and Differential Test

2**Description**

Absolute neutrophil count on day +30 after the transplantation

Timepoint

Day +30 after the transplantation

Method of measurement

Complete Blood Count and Differential Test

3**Description**

Platelet count on day +15 after the transplantation

Timepoint

Day +15 after the transplantation

Method of measurement

Complete Blood Count Test

4**Description**

Platelet count on day +30 after the transplantation

Timepoint

Day +30 after the transplantation

Method of measurement

Complete Blood Count Test

5**Description**

Absolute lymphocyte count on day +15 after the transplantation

Timepoint

Day +15 after the transplantation

Method of measurement

Complete Blood Count and Differential Test

6**Description**

Absolute lymphocyte count on day +30 after the transplantation

Timepoint

Day +30 after the transplantation

Method of measurement

Complete Blood Count and Differential Test

7**Description**

Hemoglobin concentration on day +15 after the transplantation

Timepoint

Day +15 after the transplantation

Method of measurement

Complete Blood Count Test

8**Description**

Hemoglobin concentration on day +30 after the transplantation

Timepoint

Day +30 after the transplantation

Method of measurement

Complete Blood Count Test

9**Description**

Absolute monocyte count on day +15 after the transplantation

Timepoint

Day +15 after the transplantation

Method of measurement

Complete Blood Count and Differential Test

10**Description**

Absolute monocyte count on day +30 after the transplantation

Timepoint

Day +30 after the transplantation

Method of measurement

Complete Blood Count and Differential Test

11**Description**

Time to leukocyte engraftment

Timepoint

Every day after transplantation up to the day of leukocyte engraftment

Method of measurement

Complete Blood Count Test

12**Description**

Leukocyte count on day +15 after the transplantation

Timepoint

Day +15 after the transplantation

Method of measurement

Complete Blood Count Test

13

Description

Leukocyte count on day +30 after the transplantation

Timepoint

Day +30 after the transplantation

Method of measurement

Complete Blood Count Test

14

Description

Number of days receiving G-CSF

Timepoint

On discharge

Method of measurement

Patient's hospital file

15

Description

Number of times receiving packed red blood cells

Timepoint

On discharge

Method of measurement

Patient's hospital file

16

Description

Number of times receiving platelet transfusion

Timepoint

On discharge

Method of measurement

Patient's hospital file

17

Description

Length of hospital stay

Timepoint

On discharge

Method of measurement

Patient's hospital file

18

Description

Incidence rate of engraftment syndrome

Timepoint

On discharge

Method of measurement

Patient's hospital file

19

Description

Incidence rate of fever

Timepoint

On discharge

Method of measurement

Patient's hospital file

20

Description

Length of fever

Timepoint

On discharge

Method of measurement

Patient's hospital file

21

Description

Length of severe neutropenia

Timepoint

On discharge

Method of measurement

Patient's hospital file

22

Description

Hypercalcemia

Timepoint

Two times weekly from transplantation up to day +30 after transplantation

Method of measurement

Level of serum calcium by laboratory

23

Description

Hypocalcemia

Timepoint

Two times weekly from transplantation up to day +30 after transplantation

Method of measurement

Level of serum calcium by laboratory

24

Description

Hyperphosphatemia

Timepoint

Two times weekly from transplantation up to day +30 after transplantation

Method of measurement

Level of serum phosphorus by laboratory

25

Description

Hypophosphatemia

Timepoint

Two times weekly from transplantation up to day +30 after transplantation

Method of measurement

Level of serum phosphorus by laboratory

26

Description

Serum level of vitamin D

Timepoint

Before the conditioning regimen before transplantation

Method of measurement

Laboratory kit of 25-OH-D

27**Description**

Serum level of calcitriol

Timepoint

Before the conditioning regimen before transplantation and on days +15 and +30 after transplantation

Method of measurement

Laboratory kit of 25-(OH)2-D

28**Description**

Long-term recovery of leukocytes

Timepoint

A median of 6 month after transplantation

Method of measurement

Complete Blood Count Test

29**Description**

Long-term recovery of platelets

Timepoint

A median of 6 month after transplantation

Method of measurement

Complete Blood Count Test

30**Description**

Long-term recovery of hemoglobin

Timepoint

A median of 6 month after transplantation

Method of measurement

Complete Blood Count Test

31**Description**

Relapse Incidence

Timepoint

A median of 6 month after transplantation

Method of measurement

Patient's hospital file

32**Description**

Disease-Free Survival

Timepoint

A median of 6 month after transplantation

Method of measurement

Patient's hospital file

Intervention groups**1****Description**

Oral calcitriol 0.25 mcg pearls will be administered three times daily after receiving the conditioning regimen up to day +30 after transplantation.

Category

Treatment - Drugs

2**Description**

Oral placebo pearls similarly look like the calcitriol pearls but without the active pharmaceutical ingredient will be administered three times daily after receiving the conditioning regimen up to day +30 after transplantation.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hematopoietic Stem Cell Transplantation Wards 1,2,4 of Shariati Hospital

Full name of responsible person

Dr. Kosar Raoufinejad

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Center of the Hematology and Oncology and Stem Cell Transplantation, Shariati Hospital, Teh

Full name of responsible person

Dr. Molouk Hadjibabaei

Street address

Northern Kargar Ave, Jalal Ale-ahmad Highway, Shariati Hospital

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Center of the Hematology and Oncology and Stem Cell Transplantation, Shariati Hospital, Teh

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

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Clinical Pharmacy, Faculty of
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Full name of responsible person

Dr. Kosar Raoufinejad

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City

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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