Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Kosar Raoufinejad

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
Compelete 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
Compelete 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 Pharmacy, Tehran University of Medical Sciences, Tehran,
Full name of responsible person
Dr. Kosar Raoufinejad
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Person responsible for updating data

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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