

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effects of calcitriol on the incidence rate and severity of oral mucositis in patients undergoing 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 oral mucositis in patients undergoing autologous peripheral blood hematopoietic stem cell transplantation. Patients age between 18 and 65 years with Hodgkin's lymphoma, non-Hodgkin's lymphoma, or multiple myelomas candidate for autologous 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, 80 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. Besides, serum level of 1,25-(OH)₂-D will be measured on day 14 after transplantation. Oral calcitriol 0.25mcg or placebo pearls will be administered three times daily after the conditioning regimen up to day 14 after the transplantation. All patients in both groups will receive similar regimen for prevention of oral mucositis according to standard protocol of transplantation ward. Oral mucositis will be check every day up to day 21 after transplantation or up to day recovery of mucositis. Serum calcium and phosphorous will be measured biweekly. Furthermore, liver function test (AST,ALT,AlkP) and Bun, serum Cr will be measured on a weekly and daily basis, respectively. Primary outcomes include the effect of oral Calcitriol on the incidence rate, severity and duration of oral mucositis in patients' receiving the drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052727435N2**

Registration date: **2016-07-08, 1395/04/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-08, 1395/04/18

Registrant information

Name

Alborz Soroush

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

2016-04-20, 1395/02/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of calcitriol on the incidence rate and severity

of oral mucositis in patients undergoing autologous hematopoietic stem cell transplantation: a double-blind, randomized clinical trial

2016-04-16, 1395/01/28

Ethics committee reference number
IR.TUMS.REC.1395.2402

Public title

Effects of calcitriol on the complications of hematopoietic stem cell transplantation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 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 **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

City

Tehran

Postal code

Approval date

Health conditions studied

1

Description of health condition studied

Hodgkin lymphoma

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

2

Description of health condition studied

Non-Hodgkin 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 myeloma

ICD-10 code

C90

ICD-10 code description

Multiple myeloma and malignant plasma cell neoplasms

Primary outcomes

1

Description

incidence rate of oral mucositis

Timepoint

Every day after receiveing conditionig regimen upto day 21 after transplantation

Method of measurement

visiting the oral cavitiy by clinical pharmacist

2

Description

severity of oral mucositis

Timepoint

Every day after receiveing conditionig regimen upto day 21 after transplantation or up to day of healing of oral mucositis

Method of measurement

scoring upon WHO grading system for severity of oral mucositis

3

Description

Duration of oral mucositis condition

Timepoint
Every day after receiving conditioning regimen up to day 21 after transplantation or up to day of healing of oral mucositis

Method of measurement
Daily visiting of the oral cavity by clinical pharmacist

Secondary outcomes

1

Description
Serum level of calcitriol

Timepoint
Before the conditioning regimen before transplantation and on day 14 after transplantation

Method of measurement
Laboratory kit of 1,25-(OH)₂-D

2

Description
Serum level of vitamin D

Timepoint
Before the conditioning regimen before transplantation

Method of measurement
Laboratory kit of 25-OH-D

3

Description
Incidence rate of fever

Timepoint
On discharge

Method of measurement
Patient's hospital file

4

Description
Length of fever

Timepoint
On discharge

Method of measurement
Patient's hospital file

5

Description
Number of days receiving total parenteral nutrition

Timepoint
On discharge

Method of measurement
Patient's hospital file

6

Description
Number of days receiving Analgesic drugs

Timepoint
On discharge

Method of measurement

Patient's hospital file

7

Description
Hypercalcemia

Timepoint
Two times weekly from transplantation up to day 14 after transplantation

Method of measurement
Level of serum calcium by laboratory

8

Description
hypocalcemia

Timepoint
Two times weekly from transplantation up to day 14 after transplantation

Method of measurement
Level of serum calcium by laboratory

9

Description
hyperphosphatemia

Timepoint
Two times weekly from transplantation up to day 14 after transplantation

Method of measurement
Level of serum phosphorus by laboratory

10

Description
hypophosphatemia

Timepoint
Two times weekly from transplantation up to day 14 after transplantation

Method of measurement
Level of serum phosphorus by laboratory

11

Description
Length of hospital stay

Timepoint
On discharge

Method of measurement
Patient's hospital file

12

Description
Number of days receiving antibiotics

Timepoint
On discharge

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 14 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 14 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

Alborz Soroush

Street address

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

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr. Molouk Hadjibabaei

Street address

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

City

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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

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

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

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Full name of responsible person

Alborz Soroush

Position

Resident in Pharmacotherapy

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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