Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone

+98 21 6695 4709

Email address

a_soroush@razi.tums.ac.ir

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

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
2016-04-16, 1395/01/28
Ethics committee reference number
IR.TUMS.REC.1395.2402

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

Method of measurement

Daily visiting of the oral cavitiy 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

lenght of fever

Timepoint

On discharge

Method of measurement

Patient's hospital file

5

Description

Number od days receiveing total parentral nutrition

Timepoint

On discharge

Method of measurement

Patient's hospital file

6

Description

Number of days receiveing 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 od days receiveing 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
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
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
Full name of responsible person
Alborz Soroush
Position
Resident in Pharmacotherapy
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave, Enqelab Ave
City
Tehran
Postal code
Phone
00
Fax
Email
a_soroush@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences
Full name of responsible person
Alborz Soroush
Position
Resident in Pharmacotherapy
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave, Enqelab Ave
City
Tehran
Postal code
Phone
00
Fax
Email
a_soroush@razi.tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences
Full name of responsible person
Alborz Soroush
Position
resident in pharmacotherapy
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave, Enghelab Ave, Tehran, Iran.
City
Tehran
Postal code
Phone
+98 21 6695 4709
Fax
Email
a_soroush@razi.tums.ac.ir
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