

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Efficacy of calcitriol in prevention of high dose chemotherapy induced mucositis in patients with Fanconi anemia undergoing Hematopoietic Stem Cell Transplantation

Protocol summary

Summary

This is a randomized double blind placebo controlled trial on 1-15 year old patients with Fanconi anemia undergoing Hematopoietic Stem Cell Transplantation in Shariati hospital, affiliated to Tehran University of Medical Sciences. Patients will randomly receive 0.25 mcg calcitriol or placebo once daily from the first day of chemotherapy for 14 days. Baseline serum calcium, phosphorus and 25-OH vitD levels will be measured. patients will be assessed daily regarding the onset and severity of mucositis from the first day of chemotherapy for 14 days and 3 times weekly thereafter for up to 28 days from beginning of therapy. Serum calcium and phosphorus levels will be measured twice weekly during the period of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307141030N15**

Registration date: **2013-07-16, 1392/04/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-07-16, 1392/04/25

Registrant information

Name

Mahdi Jalili

Name of organization / entity

Hematology-Oncology & SCT Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2662

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Recruitment status

Recruitment complete

Funding source

Hematology, Oncology and SCT Research Center

Expected recruitment start date

2013-08-01, 1392/05/10

Expected recruitment end date

2014-08-01, 1393/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of calcitriol in prevention of high dose chemotherapy induced mucositis in patients with Fanconi anemia undergoing Hematopoietic Stem Cell Transplantation

Public title

Calcitriol in prevention of mucositis in patients with Fanconi anemia undergoing Hematopoietic Stem Cell Transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- Patients with Fanconi anemia 2- Age limit 1-15 years 3- Patient's Parents or guardians' informed consent Exclusion criteria: 1- 25-OH vitamin D >100 ng/ml 2- Ca>10 mg/dl 3- P>4.6 mg/dl 4- give vitamin D supplementation within past three months

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **20****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**

Pharmaceutical Sciences Research Center

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2012-02-06, 1390/11/17

Ethics committee reference number

90-11-17:2-15

Health conditions studied**1****Description of health condition studied**

Fanconi Anemia

ICD-10 code

D61.0

ICD-10 code description

Constitutional aplastic anaemia

Primary outcomes**1****Description**

Severity of mucositis

Timepoint

From the first day of chemotherapy for 14 days and 3 times weekly thereafter for up to 28 days from beginning

of therapy

Method of measurement

Physical Examination

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

Duration of mucositis

Timepoint

From the first day of chemotherapy for 14 days and 3 times weekly thereafter for up to 28 days from beginning of therapy

Method of measurement

Physical Examination

2**Description**

Incidence of GVHD

Timepoint

From the first day of transplantation until the day of discharge

Method of measurement

Physical Examination

3**Description**

Severity of GVHD

Timepoint

From the first day of transplantation until the day of discharge

Method of measurement

Clinical examinations and Laboratory data

4**Description**

Incidence of Infection

Timepoint

From the first day of transplantation until the day of discharge

Method of measurement

Clinical examinations and Laboratory data

5**Description**

Duration of infection

Timepoint

From the first day of transplantation until the day of discharge

Method of measurement

Clinical examinations and Laboratory data

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

Calcitriol 0.25 mcg/d
Category
Treatment - Drugs

2

Description
Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology-Oncology and SCT Research Center
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hematology Oncology and SCT Research Center
Full name of responsible person
Zohreh Shahabi
Street address
Shariati Hospital, Kargar Ave
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hematology Oncology and SCT Research Center
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
Hematology Oncology and SCT Research Center
Full name of responsible person
Mona Sherafatmand

Position
ParmD
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Person responsible for scientific inquiries

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Hematology Oncology and SCT Research Center
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Molok Hajibabaei
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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