

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the effect of erythropoietin mouthwash in preventing the incidence and decreasing severity of mucositis in patients undergoing autologous bone marrow transplantation

Protocol summary

Summary

We will conduct a double-blind, randomized, placebo-controlled trial to evaluate the erythropoietin mouthwash effect on oral mucositis (OM) incidence and severity in 80 patients with hematological malignancies, undergoing autologous hematopoietic SCT (HSCT). A total of 80 adult patients with NHL, Hodgkin disease (HD) or multiple myeloma (MM), undergoing autologous HSCT, are needed to enroll in the study. Major inclusion criteria are age of at least 18 years old, patients with NHL, HD or MM receiving conditioning chemotherapy before autologous HSCT and signing written informed consent. Major exclusion criteria are Karnofsky performance status <70% or participation in another study using an unlicensed product. Patients will receive either erythropoietin mouthwash (50 IU/mL, 15 ml four times a day) (n = 40) or placebo (n = 40) from the starting day of high dose chemotherapy until day +14 after transplantation. OM incidence, severity and duration will be evaluated as primary study outcomes using five-grade World Health Organization (WHO) oral toxicity scale. Several indices will be assessed as secondary outcomes including the duration of ANC under 500 cells/mm³, neutrophil and platelet engraftment time, the incidence and duration of fever and length of hospital stay.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042518842N8**

Registration date: **2015-05-03, 1394/02/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-03, 1394/02/13

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation, Tehran University of Medic

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 3691

Email address

ctu@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hematology, Oncology and Stem Cell Transplantation Research Center

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of erythropoietin mouthwash in preventing the incidence and decreasing severity of mucositis in patients undergoing autologous bone marrow transplantation

Public title

Evaluation of the effect of erythropoetin mouthwash in mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: age of at least 18 years old; patients with NHL, HD or MM receiving conditioning chemotherapy before autologous HSCT; signing written informed consent. exclusion criteria: Karnofsky performance status <70% or participation in another study; using an unlicensed product.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

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

Ethic Committee Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-04-25, 1394/02/05

Ethics committee reference number

9011358003-143850

Health conditions studied

1

Description of health condition studied

multiple myeloma

ICD-10 code

c90.0

ICD-10 code description

multiple myeloma

2

Description of health condition studied

Non-Hodgkin lymphoma

ICD-10 code

C85.9

ICD-10 code description

Non-Hodgkin lymphoma, unspecified

3

Description of health condition studied

Hodgkin lymphoma

ICD-10 code

C81.9

ICD-10 code description

Hodgkin lymphoma, unspecified

Primary outcomes

1

Description

incidence, severity and duration of oral mucositis

Timepoint

The starting day of preparing chemotherapy until day +21 after transplantation

Method of measurement

Daily oral examination based on the WHO criteria for grading mucositis

Secondary outcomes

1

Description

neutrophil and platelet engraftment

Timepoint

The starting day of preparing chemotherapy until day +21 after transplantation

Method of measurement

CBC test

2

Description

Duration of neutropenia

Timepoint

The starting day of preparing chemotherapy until day +21 after transplantation

Method of measurement

CBC test

3

Description

Duration of fever due to neutropenia

Timepoint

The starting day of preparing chemotherapy until day +21 after transplantation

Method of measurement

Temperatures measured under the tongue

4**Description**

Duration of hospitalization

Timepoint

Discharge Time

Method of measurement

The number of hospitalization days

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

erythropoietin mouthwash (50 IU/mL, 15 ml four times a day from starting day of preparing chemotherapy until day +14 after transplantation

Category

Prevention

2**Description**

pelacebo mouthwash (50 IU/mL, 15 ml four times a day from starting day of preparing chemotherapy until day +14 after transplantation

Category

Placebo

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

Hematology, Oncology and Stem Cell Transplantation Research Center

Full name of responsible person

Hesamoddin Hosseinjani

Street address

Kargar Shomali St

City

Tehran

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

Hematology, Oncology and Stem Cell Transplantation Research Center

Full name of responsible person

Mohammad Vaezi

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 Stem Cell Transplantation 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**

School of Pharmacy, Tehran University of Medical Sciences

Full name of responsible person

Hesamodin Hosseinjani

Position

Board of Clinical Pharmacy

Other areas of specialty/work**Street address**

Keshavarz St

City

Tehran

Postal code**Phone**

+98 21 6643 5807

Fax**Email**

hosseinjanih@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

School of Pharmacy of Tehran University of Medical Sciences

Full name of responsible person

Molouk Hajbabaii

Position

Board of Clinical Pharmacy

Other areas of specialty/work**Street address**

N.92, kheradmand jonoubi St

City

Tehran

Postal code

Phone

00

Fax**Email**

hajibaba@tums.ac.ir

Web page address**Phone**

+98 21 8490 2669

Fax**Email**

ctu@tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**Hematology, Oncology and Stem Cell Transplantation
Research Center**Full name of responsible person**

Leyla Sharifi Aliabadi

Position

Nurse

Other areas of specialty/work**Street address**

Shariati Hosspital

City

Tehran

Postal code

14114

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*