

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of the effect of erythropoetin 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 erythropoetin 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 erythropoetin 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/mm<sup>3</sup>, 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

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##### 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 erythropoetin 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

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Research Center**Full name of responsible person**

Leyla Sharifi Aliabadi

**Position**

Nurse

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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*