

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Evaluating the safety and efficacy of N-acetylcysteine mouthwash on the prevention of mucositis in patients undergoing hematopoietic stem cell transplantation: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Evaluating the safety and efficacy of N-acetylcysteine mouthwash on the prevention of mucositis in patients undergoing hematopoietic stem cell transplantation: a double-blind randomized controlled trial

##### Design

The current clinical trial has two experimental and control groups in parallel. This phase 3 study is a double-blind, randomized study on 100 patients.

##### Settings and conduct

This study is conducted at the Research Institute of Oncology, Hematology, and Cell Therapy located in Shariati Hospital. 100 patients were included in the study and divided into two experimental and control groups. Meanwhile, patients, researchers and healthcare providers are not aware of this division. The experimental group received 2400 mg N-acetylcysteine daily and the control group received a placebo daily.

##### Participants/Inclusion and exclusion criteria

Eligibility criteria: • Patients undergoing HSCT (allogeneic and autologous) • Aged over 18 years • Informed consent of patients  
Criteria for not entering the study: • History of allergy to N-acetylcysteine or any of the components of effervescent tablets • Lack of ability of the patient to adhere to the correct use of mouthwash • Systemic intake of N-acetylcysteine • Pregnancy or lactation

##### Intervention groups

Intervention group: daily intake of 2400 mg of N-acetylcysteine as a mouthwash  
Control group: receiving daily placebo in the form of mouthwash

##### Main outcome variables

Evaluating the safety and efficacy of N-acetylcysteine mouthwash on reducing the incidence of different degrees of mucositis, especially its severe degrees (grade 3 and 4) in patients undergoing HSCT;  
Investigating the relationship between prophylactic N-

acetylcysteine mouthwash and length of hospitalization after engraftment in these patients; Introducing an effective medication to prevent of mucositis in HSCT; Introducing a potential indication of a product in market

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140818018842N42**

Registration date: **2024-09-14, 1403/06/24**

Registration timing: **prospective**

Last update: **2024-09-14, 1403/06/24**

Update count: **0**

##### Registration date

2024-09-14, 1403/06/24

##### 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

##### Expected recruitment start date

2024-09-21, 1403/06/31

##### Expected recruitment end date

2025-03-19, 1403/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the safety and efficacy of N-acetylcysteine mouthwash on the prevention of mucositis in patients undergoing hematopoietic stem cell transplantation: a double-blind randomized clinical trial

**Public title**

Evaluating the efficacy of N-acetylcysteine mouthwash on the prevention of HSCT-induced mucositis

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients undergoing hematopoietic stem cell transplantation (allogeneic and autologous) Patients aged between 18 to 65 The requirement to obtain informed consent from patients

**Exclusion criteria:**

History of allergy to N-acetylcysteine or any of the side components of effervescent tablets Lack of ability of the patient to adhere to the correct use of mouthwash (such as the possibility of not observing the timing and continuity of use or swallowing after local use) Systemic treatment with N-acetylcysteine (oral or injection) Pregnancy or lactation

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All adult patients who are admitted for hematopoietic stem cell transplantation to the Research Institute for Oncology, Hematology, and Cell Therapy, affiliated with Tehran University of Medical Sciences (TUMS), in the case of being eligible and obtaining informed consent, are included in the study and randomly assigned to Two groups of intervention and placebo. Patients are parallelly allocated into the two groups. Random list with balanced block, in blocks of four samples and considering the sample size of 100 cases with the following command: ralloc block size treat, nsubj(100)

seed(1) saving(mytrial) osize(1) init(4) idvar(study\_ID) will be prepared in Stata. The Excel list will include row number, study\_ID (including random numbers), and type of intervention (A/B). Group A is considered as intervention group and group B as placebo.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

medications were labeled according to the list and according to study\_ID generated by a third party. The complete list, including the randomization sequence and study\_ID, will be recorded in an Excel file until the end of the study. According to the study\_ID list provided to the researcher, when the patient enters the study, the labeled medication will be given to the patient by the researcher. Except for the third party, all members of the research group, including those responsible for evaluating safety, efficacy, collecting information, analyzing data, and the participating patients, are not aware of the type of the received intervention.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

research ethics committees of school of dentistry- Tehran university of medical sciences

**Street address**

Pour Sina St, District 6, Tehran, Tehran Province

**City**

Tehran

**Province**

Tehran

**Postal code**

1461884513

**Approval date**

2024-07-13, 1403/04/23

**Ethics committee reference number**

IR.TUMS.DENTISTRY.REC.1403.048

**Health conditions studied**

1

**Description of health condition studied**

oral mucositis

**ICD-10 code**

K12.3

**ICD-10 code description**

Oral mucositis (ulcerative)

## 2

### Description of health condition studied

hematopoietic stem cell transplantation

### ICD-10 code

Z94.84

### ICD-10 code description

Stem cells transplant status

## Primary outcomes

### 1

#### Description

incidence of oral mucositis

#### Timepoint

Daily for 14 days or until engraftment

#### Method of measurement

Clinical examination

### 2

#### Description

incidence of N-acetylcysteine side effects (including non-immune anaphylaxis reactions, cardiovascular reactions, skin reactions, gastrointestinal reactions)

#### Timepoint

Daily for 14 days or until engraftment

#### Method of measurement

Clinical examination

### 3

#### Description

Severity of mucositis

#### Timepoint

Daily for 14 days or until engraftment

#### Method of measurement

Patient examination and grading according to the "oral toxicity scale" of the World Health Organization (WHO)

## Secondary outcomes

### 1

#### Description

Length of hospitalization

#### Timepoint

Until discharge

#### Method of measurement

Refer to patient file

## Intervention groups

### 1

#### Description

Intervention group: Every 6 hours, 600 mg N-acetylcysteine as a mouthwash for 14 days or until engraftment

#### Category

Treatment - Drugs

## 2

### Description

Control group: Placebo mouthwash every 6 hours for 14 days or until engraftment

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Research Institute for Oncology, Hematology and Cell Therapy

##### Full name of responsible person

Bitra Shahrami

##### Street address

Shariati hospital, North Kargar Ave., Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

13135-14117

##### Phone

+98 21 8800 4140

##### Email

bita.shahrami@gmail.com

##### Web page address

<https://riohct.tums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Institute for Oncology, Hematology and Cell Therapy

##### Full name of responsible person

Mohammad Vaezi

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Shariati Hospital, North Kargar Ave., Tehran

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horcbmt@sina.tums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Research Institute for Oncology, Hematology and Cell

Therapy  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Motahareh Tahmasebi  
**Position**  
student  
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Medical doctor  
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Medical Pharmacy  
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## Person responsible for scientific inquiries

### Contact

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Assistant Professor of Clinical Pharmacy  
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Subspecialist  
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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further information.

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available