Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study the effect of spray coldamaris in recovery of oral mucositis in stem cells transplantation patients

Protocol summary

Study aim

Study the effect of spray coldamaris in recovery of oral mucositis in SCT patients

Design

This clinical trial at Ghazi Tabatabaei Hospital in Tabriz involves 50 patients with myeloma, lymphoma, and acute leukemia undergoing bone marrow transplantation. Patients are randomly split into two groups of 25. The intervention group uses FDA-approved coldamaris spray three times daily for one week if mucositis occurs, while the control group receives no treatment. The study evaluates mucositis incidence, severity, and related clinical findings, comparing outcomes between groups.

Settings and conduct

This clinical trial was conducted on 50 patients with myeloma, lymphoma, and acute leukemia who were hospitalized in the transplant ward of Ghazi Tabatabaei Hospital in Tabriz over one year. After bone marrow transplantation, patients were evaluated for the incidence and severity of mucositis and its association with clinical and paraclinical findings. The patients were randomly divided into two groups of 25: control and intervention. Patients who developed mucositis in the intervention group used coldamaris spray (FDA-approved, Sec.172.620) three times daily for one week. Their outcomes were compared with the control group, which did not use the spray. The study aimed to compare the outcomes between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with myeloma, lymphoma, and acute leukemia in the HSCT ward of Ghazi Tabatabaei Hospital, Tabriz. Exclusion criteria: Patients unwilling to use coldamaris spray, pregnant patients, and patients with unstable hemodynamics.

Intervention groups

Patients with myeloma,lymphoma, acute leukemia

Main outcome variables

Severity of oral mucositis based on the WHO scale after the use of Coldamaris spray, duration of recovery, oral feeding status, and requirement for systemic analgesics.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160415027393N3**
Registration date: **2025-07-15, 1404/04/24**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-15, 1404/04/24**
Update count: **0**

Registration date

2025-07-15, 1404/04/24

Registrant information

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Babak Nejati
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Internal medicine group of Tabriz medical university
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-10, 1404/03/20

Expected recruitment end date

2025-07-21, 1404/04/30

Actual recruitment start date

2025-06-12, 1404/03/22

Actual recruitment end date

2025-07-23, 1404/05/01

Trial completion date

2025-08-01, 1404/05/10

Scientific title

Study the effect of spray coldamaris in recovery of oral mucositis in stem cells transplantation patients

Public title

Study the effect of spray coldamaris in recovery of oral mucositis in stem cells transplantation patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

This study is a clinical study on 50 patients suffering from acute myeloma, pneumonia, and leukemia, who were hospitalized in the educational treatment ward of Shahid Ghazi Tabatabaei Hospital in Tabriz over the course of one year. After bone marrow transplantation, the mucositis incidence and severity were evaluated and its correlation with clinical and paraclinical findings was examined.

Exclusion criteria:

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of samples will be random, and the samples will be divided into control and intervention groups. In each group, 25 patients will be randomly selected. Patients who develop mucositis will use a solution of carrageenan (which has FDA approval under Sec. 172.620, and is also approved by the Iranian Food and Drug Organization and the FDA) three times daily for one week. The outcomes will be compared with a group of patients who develop mucositis but do not use this medication. A comparison of the results between the control and intervention groups will be performed.

Blinding (investigator's opinion)

Single blinded

Blinding description

In a single-blind study, the patient participates with full informed consent but does not know the specific name of the medication they are receiving among the possible treatment options.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2025-06-08, 1404/03/18

Ethics committee reference number

IR.TBZMED.REC.1404.263

Health conditions studied

1

Description of health condition studied

Study the effect of spray coldamaris in recovery of oral mucositis in stem cellstransplantation patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The primary outcome of the study is the improvement in the severity and extent of oral mucositis in patients undergoing stem cell transplantation, measured using a standard mucositis severity assessment scale (e.g., WHO Oral Mucositis Scale) on specific days after transplantation. Improvement includes the reduction of clinical symptoms of mucositis such as inflammation, pain, and oral ulcers.

Timepoint

days 1 to 21 after transplantation

Method of measurement

WHO Oral Mucositis Scale

Secondary outcomes

1

Description

The relationship between the severity of mucositis and laboratory markers, including ESR, LDH, fibrinogen, albumin, ferritin, and neutrophil count before transplantation, will be examined.

Timepoint
Evaluation with laboratory tests one to three days before transplantation
Method of measurement
Laboratory tests and Statistical methods

Intervention groups

1

Description
Intervention group: Patients with myeloma, lymphoma, leukemia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bone marrow transplant unit, Shahid Ghazi Tabatabaei Educational Therapeutic Hospital, Tabriz
Full name of responsible person
Babak nejati
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
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

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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
Because this study requires further extensive research.
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable