

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluating the effect of herbal mouthwash on preventing and treatment of oral mucositis in patients undergoing hematopoietic stem cell transplantation

Protocol summary

Summary

Purpose of study: Evaluating the effect of herbal mouthwash on preventing and treatment of oral mucositis in patients undergoing hematopoietic stem cell transplantation. Study design: triple blind, randomized, placebo controlled trial with a single recruitment center. Main inclusion criteria: All patients in Bone Marrow Transplant Center undergoing conditioning therapy. Main exclusion criteria: The patients who don't want to continue the study or allergic reactions like hives, swollen lips and inflammation of the oral mucosa caused by plants used to make the herbal mouthwash. Sample size: 60 patients. Intervention: Using herbal or placebo mouthwash 3 times daily. Intervention time: From stem cell collection day till WBC Engraftment time. Outcomes: Pain, erythema, swallowing ability and ulcer using European Bone Marrow Transplantation questionnaire, WBC Engraftment time and Platelet Engraftment time based on patient's analysis result.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105183210N3**
Registration date: **2011-10-16, 1390/07/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-16, 1390/07/24

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Faculty of Pharmacy of Shahid Beheshti University

Expected recruitment start date

2011-10-08, 1390/07/16

Expected recruitment end date

2012-10-07, 1391/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of herbal mouthwash on preventing and treatment of oral mucositis in patients undergoing hematopoietic stem cell transplantation

Public title

Evaluating the effect of herbal mouthwash on preventing and treatment of oral mucositis in patients undergoing hematopoietic stem cell transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients in Bone Marrow Transplant Center undergoing conditioning therapy. Exclusion

criteria: The patients who don't want to continue the study, Allergic reactions like hives, swollen lips and inflammation of the oral mucosa caused by plants used to prepare the herbal mouthwash.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Velenjak street

City

Tehran

Postal code

Approval date

2011-10-02, 1390/07/10

Ethics committee reference number

106

Health conditions studied

1

Description of health condition studied

oral mucositis

ICD-10 code

K12

ICD-10 code description

Stomatitis and related lesions

Primary outcomes

1

Description

Pain

Timepoint

After intervention, daily

Method of measurement

Visual pain scale

2

Description

Ulcer

Timepoint

After intervention, daily

Method of measurement

EBMT questionnaire

3

Description

Erythema

Timepoint

after intervention, daily

Method of measurement

EBMT questionnaire

4

Description

Swallowing ability

Timepoint

after intervention, daily

Method of measurement

EBMT questionnaire

5

Description

WBC Engraftment Time

Timepoint

At the end of the intervention

Method of measurement

Blood test

6

Description

Platelet Engraftment Time

Timepoint

At the end of the intervention

Method of measurement

Blood test

Secondary outcomes

1

Description

Allergic reactions

Timepoint

After intervention, daily
Method of measurement
Outbreak of hives, swollen lips and inflammation of the oral mucosa

Intervention groups

1

Description

Intervention group: treatment patients receive herbal mouthwash. patients should gargle it 3 times daily, every time diluting 1 milliliter of mouthwash in 50 milliliters water, during the time of their hospitalization (about 20 days)

Category

Treatment - Drugs

2

Description

Control group: placebo patients receive placebo mouthwash. patients should gargle it 3 times daily, every time diluting 1 milliliter of mouthwash in 50 milliliters water, during the time of their hospitalization (about 20 days)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr. Maria Tavakoli Ardakani

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Faculty of Pharmacy of Shahid Beheshti University of Medical Science

Full name of responsible person

Dr. Afshin Zarghi

Street address

Faculty of Pharmacy, Valiasr street, Nyayesh Junction

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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

Vice chancellor for research of Faculty of Pharmacy of Shahid Beheshti University of Medical Science

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

Faculty of Pharmacy, Shahid Beheshti University Of Medical Sciences

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Sara Ghasemi

Position

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Other areas of specialty/work

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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