Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Transplantion qustionnaire, 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

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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 intevention, daily
Method of measurement
EBMT qustionnaire

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

City

Tehran

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

Full name of responsible person

Sara Ghasemi

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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