Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of efficacy of mouthwash and oral tablet of propolis on prevention and treatment of mucositis in hematopoietic stem cell transplantation recipients

Protocol summary

Study aim

The main purpose is to evaluate the effect of mouthwash and oral tablet of propolis in preventing mucositis, assessing the time and duration of mucositis, reducing the severity of mucositis and reducing infection (according to the results of microbial culture)

Design

A randomized triple blind clinical trial with a parallel group design of 84 patients, who underwent autologous bone marrow transplantation

Settings and conduct

This study perform in the bone marrow transplant department of Ayatollah Taleghani Educational Hospital in a randomized, triple blind (patient, statistical analyzer and researcher) in two groups of drug and placebo

Participants/Inclusion and exclusion criteria

All patients hospitalized in bone marrow transplantation and patients undergoing chemotherapy. Patient satisfaction and cooperation to participate in the study. Ability to communicate and answering questions during the period of mucositis. Patients from previous chemotherapy or radiotherapy should not have oral mucositis and should be included in the study from the beginning of treatment

Intervention groups

Intervention group: receiving propolis, in amounts of 7.5 ml, from the mouthwash form, every 12 hours, for 15 days and one tablet, from the oral form, every 8 hours, for 10 days, along with receiving standard mucositis treatment, from the first day of chemotherapy until engraftment Control group: receiving placebo, in amounts of 7.5 ml, from the mouthwash form, every 12 hours, for 15 days and one tablet, from the oral form, every 8 hours, for 10 days, along with receiving standard mucositis treatment, from the first day of chemotherapy until engraftment

Main outcome variables

Incidence of mucositis; Duration of mucositis; Intensity of mucositis; The amount of narcotics analgesics needed; The amount of antibiotics needed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N24**
Registration date: **2021-11-11, 1400/08/20**
Registration timing: **prospective**

Last update: **2021-11-11, 1400/08/20**
Update count: **0**

Registration date

2021-11-11, 1400/08/20

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

Expected recruitment start date

2021-11-15, 1400/08/24

Expected recruitment end date

2022-11-16, 1401/08/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of efficacy of mouthwash and oral tablet of propolis on prevention and treatment of mucositis in hematopoietic stem cell transplantation recipients

Public title
Efficacy and safety of mouthwash and oral tablet of propolis on the mucositis in hematopoietic stem cell transplantation recipients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients hospitalized in bone marrow transplantation who received conditioning chemotherapy regimen Patient satisfaction and cooperation to participate in the study Ability to communicate and answering questions during the period of mucositis Patients from previous chemotherapy or radiotherapy should not have oral mucositis and should be included in the study from the beginning of treatment
Exclusion criteria:
History of allergies to propolis or other components of mouthwash and oral tablet History of asthma, seasonal allergies and history of aspirin allergy Taking anticoagulant drugs such as warfarin Fasting blood sugar above 150 mg/dl
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the randomization method is permuted block technique randomization and the randomization unit is cluster. The allocation and distribution of blocks is done with the help of random allocation software and each person is assigned a code created with the help of software. In fact, we have two groups of 42 patients, one receiving medication and one receiving placebo. Each group also has 6 blocks, which are transplant type blocks, including autologous and allogeneic transplants, and age blocks, including patients aged 20 to 40 years, 40 to 60 years, and over 60 years. Each block contains 7 people. The variables of blocks include the age of patients and their type of transplantation, so that patients are divided into two groups of 42 people based on age and type of transplantation, each group consists of 6 blocks of 7 people.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, participants, principle investigator initiated trials, data collectors, outcome assessors are unaware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Faculty of Pharmacy - Shahid Beheshti University of Medical Sciences
Street address
Faculty of Pharmacy, Shahid Beheshti University of Medical Science, Valiasr St., Hashemi Rafsanjani Highway intersection., Tehran, Iran.
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Approval date
2021-03-13, 1399/12/23
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1399.403

Health conditions studied

1

Description of health condition studied
Oral mucositis
ICD-10 code
K12.31
ICD-10 code description
Oral mucositis (ulcerative) due to antineoplastic therapy

2

Description of health condition studied
Gastrointestinal mucositis
ICD-10 code
K92.81
ICD-10 code description

Gastrointestinal mucositis (ulcerative)

Primary outcomes

1

Description
Mucositis
Timepoint
First day of chemotherapy until engraftment day
Method of measurement
WHO scoring system

Secondary outcomes

1

Description
Fever grade
Timepoint
From the first day of chemotherapy until engraftment time
Method of measurement
Submit a fever above 38.3 °C for patients

2

Description
The need for total parenteral nutrition (TPN)
Timepoint
During the study period
Method of measurement
Sign the days of parenteral nutrition intake

3

Description
The amount of narcotics analgesics needed
Timepoint
Daily
Method of measurement
Patient's medication list

4

Description
The amount of antibiotics needed
Timepoint
Daily
Method of measurement
Patient's medication list

Intervention groups

1

Description
Intervention group: receiving propolis, in amounts of 7.5 ml, from the mouthwash form, every 12 hours, for 15 days and one tablet, from the oral form, every 8 hours, for 10 days, along with receiving standard mucositis treatment, from the first day of chemotherapy until engraftment
Category
Treatment - Drugs

2

Description
Control group: receiving placebo (including neutral and permitted additives with similar characteristics to mouthwash and oral propolis tablets), in amounts of 7.5 ml, from the mouthwash form, every 12 hours, for 15 days and one tablet, from the oral form, every 8 hours, for 10 days, along with receiving standard mucositis treatment, from the first day of chemotherapy until engraftment
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
The bone marrow transplantasion departmant of Taleghani hospital
Full name of responsible person
Mahsa Khanzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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http://pharmacy.sbmu.ac.ir/index.jsp?pageid=5649&p=1

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahsa Khanzadeh
Position
Pharmacy student
Latest degree
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Primary outcome data after making unrecognizable will be released

When the data will become available and for how long

6 months after publishing the results primary outcome data will be released

To whom data/document is available

Researchers after allowance of corresponding author could have the permission to have the data

Under which criteria data/document could be used

Performing any analysis will be allowed only with the permission of corresponding author

From where data/document is obtainable

Corresponding author

What processes are involved for a request to access data/document

After requesting to reach data, corresponding author will check the allowance, then the researcher will be informed about it

Comments