Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Effect of Propolis Mouthwash in the Prevention of the Chemotherapy Induced Mucositis

Protocol summary

Summary

The aim of this study is to evaluate the effect of Propolis mouthwash to prevent mucoitis caused by chemotherapy. This randomized clinical trial conducted among 40 adult patients (20-60 years) who referred to Hematology and Oncology Department of the Shahid Sadoughi Hospital for chemotherapy and at first courses developed mucoitis. Patients randomly assigned to intervention and control groups (placebo) each containing 20 patients. Propolis mouthwash in the intervention group (Mashhad Tak Toos Soren Co, 30% extracts) and the placebo control group (Mashhad Tak Toos Soren Co, Water and Additives) 24 hours before the onset of the second course of chemotherapy for 3 times per day every 8 hours for 14 days after completion of the course. At the 7th and 14th days the patient's mouth examined in a light and their ability to eat and drink recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022924959N2**
Registration date: **2016-03-18, 1394/12/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-18, 1394/12/28

Registrant information

Name

Maryam Kheirandish

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Propolis Mouthwash in the Prevention of the Chemotherapy Induced Mucositis

Public title

Evaluation of the Effect of Propolis Mouthwash in the Prevention of Mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Adults aged 20-60 years old; patients referred to the Hematology and Oncology Department of the Shahid Sadoughi Hospital for chemotherapy and at first courses developed mucositis. Exclusion criteria: Outside the specified age range; sensitivity to Propolis mouthwash; the worsening condition of the patient

Age

From **20 years** old to **60 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Sadoughi University of Medical Sciences
Street address
Vice Chancellor for Research, Headquarter of Yazd University of Medical Sciences, Bahonar Square
City
Yazd
Postal code
Approval date
2015-01-10, 1393/10/20
Ethics committee reference number
Ssu. 176/3456

Health conditions studied

1

Description of health condition studied
mucositis
ICD-10 code
K12.0
ICD-10 code description
K12.3

Primary outcomes

1

Description
Ability to eat and drink
Timepoint
Seventh and fourteenth days
Method of measurement
Ask from the Patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mouthwash Propolis (Mashhad Tak Toos Soren Co, 30% extracts) Control group: Placebo (Mashhad Tak Toos Soren Co, Water and Additives)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology and Oncology Department, Shahid Sadoughi Hospital
Full name of responsible person
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr. Amir Houshang Mehrparvar
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Vice Chancellor for Research, Headquarter of Yazd University of Medical Sciences, Bahonar Square
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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
Shahid Sadoughi University of Medical Sciences
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
Shahid Sadoughi University of Medical Sciences

Full name of responsible person
Maryam Jalili Sadr Abad

Position
Resident of Oral and Maxillofacial Surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

Contact

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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