

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 35 3724 9104

Email address

dr.hashemi@ssu.ac.ir

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 addressVice 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

Street addressVice Chancellor for Research, Headquarter of Yazd
University of Medical Sciences, Bahonar Square**City**

Yazd

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**Street address**

Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences

City

Yazd

Postal code**Phone**

+98 35 3822 9104

Fax**Email**

hn_1364@yahoo.com

Web page address

+98 35 3726 3733

Fax**Email**

dr.njalili@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Hossein Neamatzadeh

Position**Other areas of specialty/work****Street address**

Hematology and Oncology Research Center, Shahid Sadoughi Hospital

City

Yazd

Postal code**Phone**

+98 35 3822 9104

Fax**Email****Web page address**

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Karbasi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences

City

Yazd

Postal code**Phone**

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