

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluating the effect of propolis tablets on chemotherapy induced oral mucositis

#### Protocol summary

##### Summary

The goal of this randomized clinical trial is the evaluation of effect of propolis tablet on prevention and treatment of chemotherapy induced oral mucositis. This is a randomized double-blind and placebo-control study. Fifty patients with colon cancer and under the Folfox chemotherapy regimen who are referred to Imam Khomeini hospital in Sari are randomly placed in 2 groups of 25 people (intervention and control group). The first group of patients receive 2 propolis tablets daily up to 21 days (Tab 50mg). The second group receive placebo. All patients are visited at first and then every week until 3 weeks by oral diseases specialist and oral mucositis is recorded according to WHO and OMAS indices.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017060933722N2**  
Registration date: **2017-07-02, 1396/04/11**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-07-02, 1396/04/11

##### Registrant information

###### Name

Tahereh Molania

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

###### Expected recruitment start date

2017-07-06, 1396/04/15

###### Expected recruitment end date

2017-09-06, 1396/06/15

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluating the effect of propolis tablets on chemotherapy induced oral mucositis

###### Public title

Evaluating the effect of propolis tablets on chemotherapy induced oral mucositis

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: Patients with colon cancer who receive Folfox chemotherapy regimen with oral mucositis at grade 0 level from WHO indice. Exclusion criteria: Chronic liver failure(stage2,3); Chronic kidney disease(stage4,5); Oral signs and symptoms of any type of allergy and sensitivity to honey and propolis.

###### Age

From **18 years** old to **75 years** old

###### Gender

Both

**Phase**

4

**Groups that have been masked***No information***Sample size**

Target sample size: 50

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Table of random number

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**Ethics committee of Mazandaran University of  
Medical Sciences**Street address**Vice chancellor for research, The martyr Motahhari  
square, Street teacher**City**

Sari

**Postal code****Approval date**

2017-06-19, 1396/03/29

**Ethics committee reference number**

IR.MAZUMS.REC.96.2995

**Health conditions studied****1****Description of health condition studied**

chemotherapy induced oral mucositis

**ICD-10 code**

k12.3

**ICD-10 code description**

oral mucositis ( drug induced )

**Primary outcomes****1****Description**

Severity of oral mucositis

**Timepoint**

once a week ( weekly )

**Method of measurement**

according to WHO and OMAS indices

**Secondary outcomes****1****Description**

-

**Timepoint**

-

**Method of measurement**

-

**Intervention groups****1****Description**Intervention group: administration of oral propolis tablet  
50mg,twice a day(BID) up to 21 days.**Category**

Treatment - Drugs

**2****Description**

Control group: receives placebo

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Parisa Ghodrati

**Street address**

Amirmazandarani street, Sari

**City**

Sari

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Mazandaran university  
of medical sciences**Full name of responsible person**

Ahmad Ali Enayati

**Street address**Vice chancellor for research, The martyr Motahhari  
square, Street teacher**City**

Sari

**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, Mazandaran 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**  
Sari Dentistry College  
**Full name of responsible person**  
Parisa Ghodrati  
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student of PHD general dentistry  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Maede Salehi Sarookolaei  
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Oral Diseases specialist-Assistant professor

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## Person responsible for updating data

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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*