Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 speciallist and oral mucositis is recorded according to WHO and OMAS indices.

General information

Acronym

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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

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Tahereh Molania
Name of organization / entity
Mazandaran University of Medical Sciences
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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 Universiyy 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
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Timepoint
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Method of measurement
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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 pelacebo
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
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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
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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