Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The Effect of Iranian Propolis on Radiation- Induced Mucositis

Protocol summary

Summary

The purpose of this study was to evaluate the effects of Iranian propolis on the oral mucositis induced by radiation therapy in patients with oral cancer. This is a randomized , double-blind , placebo- controlled , single-center , phase one trial. Sixty patient with head and neck malignancy who are referred to Shahid Rajaee Hospital for radiation therapy enter the trial. Inclusion criteria are: received dose of at least 4000 Gy and being oral cavity in the field of radiation. Exclusive criteria are: presence of any systemic diseases such as diabetes , hypertension , oral active infection , active collagen vascular disease , smoking , presence of any type of allergy and sensitivity to honey and its products , history of radiation therapy to the head and neck area , receiving chemotherapy at the same time and stopping the radiation because of severe mucositits. The patient should not use honey and wax accidentally during the study. Patients are allocated in two groups of 30 and are matched according to sex and type of cancer. The first group will receive 300 mg propolis 8 times a day since starting radiation. The second group will received placebo 8 times a day since starting radiation. All patients will visit and evaluate weekly and oral mucositits will record according to WHO and OMAS indices at the end of each week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081018753N1**
Registration date: **2015-01-23, 1393/11/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-23, 1393/11/03

Registrant information

Name
Mina Motallebnejad
Name of organization / entity
Babol University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 911 111 4191
Email address
m.motallebnejad@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

approved fund by deputy of research & technology of Babol University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Iranian Propolis on Radiation- Induced Mucositis

Public title

The Effect of Iranian Propolis on Radiation- Induced oral ulceration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: oral cancer ; received dose of at least 4000 Gy ; being oral cavity in the field of radiation. Exclusive criteria are: presence of any systemic diseases such as diabetes , hypertension ; oral active infection ; active collagen vascular disease ; smoking ; presence of

any type of allergy ; sensitivity to honey and its products ; history of radiation therapy to the head and neck area ; receiving chemotherapy at the same time ; stopping the radiation because of severe mucositits.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
University of Medical Sciences

Street address
University of Medical Sciences, Ganjafroz Street, Babol

City
Babol

Postal code
4717641367

Approval date
2013-12-17, 1392/09/26

Ethics committee reference number
30/3480/ز/ب

Health conditions studied

1

Description of health condition studied
Mucositis

ICD-10 code
k12.3

ICD-10 code description
Oral mucositis (ulcerative)

Primary outcomes

1

Description
Mucositis severity

Timepoint
weekly

Method of measurement
By OMAS & WHO indices

Secondary outcomes

empty

Intervention groups

1

Description
Prpolis , Tab 300 mg, oral, 8 times day , 6 weaks

Category
Treatment - Drugs

2

Description
placebo(lactose),Tab 300 mg , 8 times a day ,six weaks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Radio Oncology (Sh R- Hospital)

Full name of responsible person
Dariosh Moslemi

Street address
Shahid Rajai- Hospital, Babolsar

City
Babolsar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Ali Akbar Moghadamnia

Street address
Babol University of Medical Sciences- Deputy of research & technology

City
Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Fateme Sayyadi
Position
Post graduate student
Other areas of specialty/work
Street address
School of Dentistry, Babol
City
Babol
Postal code
Phone
+98 11 3230 0370
Fax
Email
f.sayyadi90@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mina Motallebnejad
Position
Associate
Other areas of specialty/work
Street address
Dental School, Babol University of Medical Sciences
City
Babol
Postal code
Phone
+98 112229408
Fax
Email
mmotallebnejad@yahoo.com
Web page address

Person responsible for updating data

Contact

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