Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effect of propolis solution on prevention and treatment of oral mucositis in patients undergoing head and neck radiotherapy.

Protocol summary

Summary

The goal of this randomized clinical trial is evaluation the effect of propolis solution on prevention and treatment of oral mucositis in patients undergoing the first episode of head and neck radiotherapy . This study is a randomized , double-blind and placebo- control. 60 patient who are referred to Imam Hossein Hospital for radiation therapy were randomly placed in two groups of 30 people (intervention and control group). The first group of patients will receive 5 drops of propolis solutionTDS (16 mg TDS) for one month.The second group will received placebo. All patients will visit and evaluate weekly by radiotherapist and oral mucositits will record according to WHO, OMAS and NCI indices.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010225726N2**
Registration date: **2016-05-18, 1395/02/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-18, 1395/02/29

Registrant information

Name
Farzaneh Dastan
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Pharmacy School of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of propolis solution on prevention and treatment of oral mucositis in patients undergoing head and neck radiotherapy.

Public title

Effect of propolis solution on prevention and treatment of oral mucositis in patients undergoing head and neck radiotherapy.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing the first episode of head and neck radiotherapy without any oral mucositis.Exclusion criteria: Chronic liver failure (Stage II & III); Chronic kidney disease (Stage IV & V); oral active infection; active collagen vascular disease; presence of any type of allergy and sensitivity to honey and propolis.

Age

No age limit

Gender

Both

Phase
N/A
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
Shahid Beheshti University of Medical Sciences
Street address
Tehran,Valiasr Street intersection of Niayesh Highway
City
Tehran
Postal code
Approval date
2016-03-01, 1394/12/11
Ethics committee reference number
IR.SBMU.PHNM.1394.309

Health conditions studied

1

Description of health condition studied
oral mucositis
ICD-10 code
K12.3
ICD-10 code description
موکوزیت دهانی ناشی از رادیوتراپی

Primary outcomes

1

Description
Mucositis severity
Timepoint
weekly
Method of measurement
Based on the criteria of NCI, OMAS & WHO

Secondary outcomes

1

Description
Pain
Timepoint
Once a week for a month
Method of measurement
Based on the pain scale grade classification(0-10)

2

Description
Dysphagia
Timepoint
Once a week for a month
Method of measurement
Clinical evaluation and Questionnaire

Intervention groups

1

Description
Intervention: administration of propolis , oral solution ,5 dropsTDS(16mg TDS), duration of intervention is one month
Category
Prevention

2

Description
Control group receives placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Street address
Tehran,Shahid madani street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzaneh Dastan
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Tehran-Valiasr Street intersection Niayesh Highway

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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 Beheshti University of Medical Sciences
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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