

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

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

Protocol summary

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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 mucositis will record according to WHO, OMAS and NCI indices.

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

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

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

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

Street address

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

Full name of responsible person
Samaneh Dodge

Position
PharmD. Student of Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Farzaneh Dastan

Position

Assistant professor, Clinical pharmacy specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farzaneh Dastan

Position
Assistant professor Clinical pharmacy specialist

Other areas of specialty/work

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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