# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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
**Country**
Iran (Islamic Republic of)
**Phone**
+98 912 270 5933
**Email address**
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**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
**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
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## Person responsible for scientific inquiries

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Assisstant professor, Clinical pharmacy specialist
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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*