

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluating and comparing the effect of systemic and local use of Propolis in oral mucositis resulting from radiotherapy

#### Protocol summary

##### Study aim

Comparison & Evaluation Of Localized & Generalized Effect of Using Propolis On Oral Mucositis Resulting From Radiotherapy with placebo; Randomized Clinical Trial

##### Design

Parallel, triple blinded, Randomized clinical trial

##### Settings and conduct

72 patients with head and neck cancer are randomly divided into 3 groups. A: local use of propolis and systemic use of placebo B: systemic use of propolis and local use of placebo C: local and systemic use of placebo they starts using the mouthwash and drugs, when starting the radiotherapy and stops 2 weeks after finishing their radiotherapy. oral signs are recorded by a blind researcher based on WHO scales. ELISA kits are used to analyze TNF in saliva at baseline and at the end of radiotherapy.

##### Participants/Inclusion and exclusion criteria

head and neck cancer requiring radiotherapy mucositis exclusion criteria: weak patients' cooperation allergic reaction to propolis

##### Intervention groups

Local use of propolis and systemic use of placebo, Local use of placebo and systemic use of propolis, Local and systemic use of placebo

##### Main outcome variables

Local or systemic use of propolis, Severity of mucositis, Incidence of mucositis, Onset of mucositis, Measurement of TNF- $\alpha$  in saliva

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161024030475N4**

Registration date: **2019-07-21, 1398/04/30**

Registration timing: **retrospective**

Last update: **2019-07-21, 1398/04/30**

Update count: **0**

##### Registration date

2019-07-21, 1398/04/30

##### Registrant information

###### Name

Mitra Askari

###### Name of organization / entity

Tehran University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5585 1131

###### Email address

m-askari@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2017-01-20, 1395/11/01

##### Actual recruitment start date

2015-08-23, 1394/06/01

##### Actual recruitment end date

2018-01-21, 1396/11/01

##### Trial completion date

2018-03-21, 1397/01/01

##### Scientific title

Evaluating and comparing the effect of systemic and local use of Propolis in oral mucositis resulting from radiotherapy

##### Public title

effect of propolis on oral mucositis resulting from radiotherapy

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

head and neck cancer requiring radiotherapy mucositis

### Exclusion criteria:

weak patients' cooperation allergic reaction to propolis

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **72**

Actual sample size reached: **83**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization method: Simple randomization, Randomization Unit: individual, Randomization tool: random number table. There is not allocation concealment.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

the producing company were asked to produce the propolis pills and placebo pill with the same appearance. Propolis and placebo mouthwash were also produced with the same color and in the same bottles. the drugs were divided into 3 separate groups. one containing placebo pills and propolis mouthwash, one containing placebo mouthwash and propolis pills and the other one containing placebo pills and mouthwash. on each bottle number 1, 2 or 3 were written. in a sealed letter the content of each group were revealed. patients, researcher and statistic expert were blinded

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehransity of Medical Sciences

##### Street address

tehran TUMS complex

## City

tehran

## Province

Tehran

## Postal code

1212232334

## Approval date

2015-07-23, 1394/05/01

## Ethics committee reference number

IR.TUMS.REC.1395.2647

## Health conditions studied

### 1

#### Description of health condition studied

Oral mucositis (ulcerative) due to radiation

#### ICD-10 code

K12.33

#### ICD-10 code description

Oral mucositis (ulcerative) due to radiation

## Primary outcomes

### 1

#### Description

mucositis severity and percentage

#### Timepoint

baseline / 2 weeks after completing radiotherapy

#### Method of measurement

based on WHO

### 2

#### Description

incidence of mucositis

#### Timepoint

baseline

#### Method of measurement

starts 1-2 weeks after radiotherapy and is determined by clinical assessment.

### 3

#### Description

TNF in saliva

#### Timepoint

baseline/ 2 weeks after completing radiotherapy

#### Method of measurement

ELISA Kis

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: local propolis and systemic placebo

**Category**

Treatment - Drugs

**2****Description**

Intervention group: systemic propolis and local placebo

**Category**

Treatment - Drugs

**3****Description**

Control group: local and systemic placebo

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shohada-ye- haft-e tir hospital

**Full name of responsible person**

mitra askari

**Street address**

shahid rajaii street

**City**

rey city

**Province**

Tehran

**Postal code**

2324545465

**Phone**

+98 21 5590 9051

**Email**

iranuniversity@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

mitra askari

**Street address**

tehran TUMS complex

**City**

tehran

**Province**

Tehran

**Postal code**

1212232334

**Phone**

+98 21 8898 7667

**Email**

M\_askari@Sina.tums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Arayeh maleki

**Position**

general practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

TUMS complex

**City**

tehran

**Province**

Tehran

**Postal code**

1212232334

**Phone**

+98 21 8898 7667

**Email**

maleki.arayeh@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

arayeh maleki

**Position**

general practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

tehran TUMS complex

**City**

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**Province**

Tehran  
**Postal code**  
1212232334  
**Phone**  
+98 21 8898 7667  
**Email**  
maleki.arayeh@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
arayeh maleki  
**Position**  
general practionor  
**Latest degree**  
Medical doctor  
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**Street address**  
tehran TUMS complex  
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tehran  
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**Postal code**  
1212232334  
**Phone**  
+98 21 8898 7667  
**Email**  
maleki.arayeh@gamil.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

data will be shared

### When the data will become available and for how long

2019

### To whom data/document is available

everybody

### Under which criteria data/document could be used

no condition

### From where data/document is obtainable

send an email: maleki.arayeh@gmail.com

### What processes are involved for a request to access data/document

Through an email explain your request and the reason for needing the data. in 2 weeks the data will be send.

### Comments