

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- α 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 Tehranrsity 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

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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

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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

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

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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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