Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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 apperance. Propolis and placebo mouthwash were also produced with the same color and in the same bottels. the drugs were divided into 3 seperate groups. one contianing placebo pills and propolis mouthwash, one contianing placebo mouthwash and propolis pills and the other one containing placebo pills and mouthwash. on each bottel nomber 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
Postal code
2324545465
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+98 21 5590 9051
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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1212232334
Phone
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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
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Person responsible for updating data

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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