Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the effect of curcumin oral gel (curcuma longa) on radiotherapy-induced mucositis in patients with head and neck cancer

Protocol summary

Summary
The objective of this double-blind interventional, placebo controlled study was to evaluate effect of curcumin oral gel on radiotherapy-induced mucositis in patients with head and neck cancer. 37 patients were divided into two groups by balanced block randomization method to receive curcumin oral gel (intervention group) or placebo (control group). During 8-week period of radiotherapy, all the patients were examined once a week and any erythema, ulcer or mouth burn (VAS) was recorded by a blind examiner. Finally, results were compared between groups.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT138904064255N1**
Registration date: **2009-01-20, 1387/11/01**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2009-01-20, 1387/11/01

Registrant information
Name
Armaghan Amirian
Name of organization / entity
Tehran university of medical sciences, Dental school
Country
Iran (Islamic Republic of)
Phone
+98 21 6611 2406
Email address
amansourian@sina.tums.ac.ir

Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2009-01-20, 1387/11/01
Expected recruitment end date
2009-04-21, 1388/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of curcumin oral gel (curcuma longa) on radiotherapy-induced mucositis in patients with head and neck cancer

Public title
Evaluating the effect of curcumin oral Gel on radiotherapy-induced mucositis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients older than 18 years, presence of head and neck cancer, minimum dose of radiation therapy 50 gy to induce mucositis, ability to use oral gel before radiotherapy session, signing informed consent
Exclusion criteria: suffering from any kind of oral disease such as active oral infection, ulcer, receiving chemotherapy combined with radiotherapy, inability to use oral gel
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
2-3
Groups that have been masked

No information

Sample size
Target sample size: **37**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran university of medical sciences

Street address
Vice-chancellor for Research, Tehran University of Medical Sciences, Qods street, Keshavarz Blvd-Tehran,Iran

City
Tehran

Postal code

Approval date
2009-06-22, 1388/04/01

Ethics committee reference number
9170

Health conditions studied

1

Description of health condition studied
oral mucositis (radiotherapy-induced mucositis)

ICD-10 code
K13.7

ICD-10 code description
Other and unspecified lesions of oral mucosa

Primary outcomes

1

Description
erythema

Timepoint
once a week during radiotherapy period

Method of measurement
milimeter

2

Description
oral mucositis grade

Timepoint
once a week during radiotherapy period

Method of measurement
clinical examination

3

Description
mouth burn

Timepoint
once a week during radiotherapy period

Method of measurement
visual analogue scale

4

Description
oral ulcer

Timepoint
once a week during radiotherapy period

Method of measurement
clinical examination

Secondary outcomes

1

Description
side effects

Timepoint
once a week during radiotherapy period

Method of measurement
asking the patient

Intervention groups

1

Description
curcumin oral gel, 3 times a day, each time 5cc, keep in the mouth for a minute

Category
Treatment - Drugs

2

Description
placebo oral gel, 3 times a day, each time 5 cc, keep in mouth for a minute

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Hospital, cancer institute

Full name of responsible person

Armaghan Amirian

Street address

Imam khomeini Hospital, Dr Gharib street,Tohid Sq,Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of medical sciences

Full name of responsible person

Resaerch Departmen

Street address

Vice-chancellor for Research, Tehran University of medical sciences, Qods street, Keshavarz blvd, Tehran, Iran

City

Tehran

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

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

Tehran University of medical sciences, dental school

Full name of responsible person

Dr. Arash Mansourian

Position

Assistant Professor

Other areas of specialty/work

Street address

Tehran university of medical sciences, Qods street, Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 6611 2439

Fax

Email

amansourian@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of medical sciences, Dental school

Full name of responsible person

Dr. Arash Mansourian

Position

Assistant professor

Other areas of specialty/work

Street address

Tehran university of medical sciences, Qods street, Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 6611 2439

Fax

Email

amansourian@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Armaghan Amirian

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

armaghan.amirian@gmail.com

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