

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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)

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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

Research Department

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

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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