

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Assessing the preventing and therapeutic effect of curcumin in radiotherapy-induced mucositis of head and neck cancers

Protocol summary

Study aim

Determination of the preventing and therapeutic effect of curcumin in radiotherapy-induced mucositis of head and neck cancers

Design

A randomized, double-blinded, clinical trial(phase III) for 40 patients has been designed. Seal envelope will be used to randomize. Randomization is performed using a computer-generated random number table.

Settings and conduct

This double-blind randomized clinical trial is conducted at Mashhad Dental School, Iran. Since the apparent appearance of the drugs is not the same, curcumin and placebo are prepared and coded by the clinical pharmacologist in the same pharmaceutical package and code decoding takes place during statistical analysis. Participants and care providers and assessing outcomes and the statistician are blinded to the type of drug because drugs are placed in similar seal envelope packs.

Participants/Inclusion and exclusion criteria

Inclusion criteria were the following: minimum age of 18 years, presence of head and neck cancer, radiation therapy of 50 Gy or greater, at least 50% of patient's oral cavity in the field of radiation, and willing to be a part of the study and sign the informed consent. Exclusion criteria were the following: the history of previous radiation therapy or chemotherapy, chemotherapy protocol in addition to radiotherapy, any allergy to condiments, especially "Turmeric root", having a pre-existing oral disease such as an active oral infection or an oral ulceration.

Intervention groups

The study group: 80 mg/d oral curcumin (1 capsule of SinaCurcumin® 80 per day), during radiotherapy. The control group: placebo tablets (containing lactose) once daily, during radiotherapy.

Main outcome variables

Severity of mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039318N2**

Registration date: **2018-05-23, 1397/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-23, 1397/03/02**

Update count: **0**

Registration date

2018-05-23, 1397/03/02

Registrant information

Name

Ala Ghazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9501

Email address

ghazial@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-27, 1397/02/07

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the preventing and therapeutic effect of curcumin in radiotherapy-induced mucositis of head and neck cancers

Public title

Assessing the preventing and therapeutic effect of curcumin mucositis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria were the following: minimum age of 18 years, presence of head and neck cancer, radiationtherapy of 50 Gy or greater, at least 50% of patient's oral cavity in the field of radiation, and willing to be a part of the study and sign the informed consent..

Exclusion criteria:

Exclusion criteria were the following: the history of previous radiation therapy or chemotherapy, chemotherapy protocol in addition to radiotherapy, any allergy to condiments, especially "Turmeric root", having a pre-existing oral disease such as an active oral infection or an oral ulceration.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups, namely the Study and Control groups. Randomization is performed using a computer-generated random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, since the apparent appearance of the drugs is not the same, curcumin and placebo are prepared and coded by the clinical pharmacologist in the same pharmaceutical package and code decoding takes place during statistical analysis. The prepared medicine packs are the same for the two group. Packages are randomly delivered to patients. The participants and care providers and assessing outcomes and the statistician are blinded to type of drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

دانشگاه علوم پزشکی مشهد- کمیته دانشکده ای اخلاق در پژوهشهای انسانی

Street address

Mashhad Dental School, Azadi Square, Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

911735984

Approval date

2014-07-12, 1393/04/21

Ethics committee reference number

IR.MUMS.REC.1393.105

Health conditions studied**1****Description of health condition studied**

oral mucositis

ICD-10 code

k12

ICD-10 code description

Stomatitis and related lesions

Primary outcomes**1****Description**

The effect of curcumin on severity of mucositis

Timepoint

Before the initiation of radiotherapy and then on days 7, 14, 21, 28, 35 and 42 of the radiotherapy course

Method of measurement

the National Cancer Institute Common Toxicity Criteria version 2 scale (NCI CTC v.2)

Secondary outcomes**1****Description**

The effect of curcumin on the onset of mucositis

Timepoint

Before the initiation of radiotherapy and then on days 7, 14, 21, 28, 35 and 42 of the radiotherapy course

Method of measurement

the National Cancer Institute Common Toxicity Criteria version 2 scale (NCI CTC v.2)

Intervention groups

1

Description

Intervention group:80 mg/d oral curcumin (1 capsule of SinaCurcumin® 80 per day), during radiotherapy (6 weeks). Each soft gel of SinaCurcumin® contains 80 mg of curcumin in the form of nano-micelle.

Category

Treatment - Drugs

2

Description

Control group: placebo tablets (containing lactose) once daily during radiotherapy. prepared by a pharmacologist colleague

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and maxillofacial Diseases Department of Mashhad Dental School

Full name of responsible person

Dr Zahra Delavarian

Street address

Mashhad Dental School, Azadi Square, Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Email

delavarianz@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

دکتر محسن تفقدي

Street address

خیابان دانشگاه، دانشگاه علوم پزشکی مشهد

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Phone

+98 51 3882 3255

Email

tafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ala Ghazi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Phone

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Delavarian

Position

Professor

Latest degree

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Dentistry

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Razavi Khorasan

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9177948959

Phone

+98 51 3882 9501

Email

delavarianz@mums.ac.ir

Web page address**Email**

ghazial@mums.ac.ir

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some data including demographic properties, signs and symptoms

When the data will become available and for how long

Two months after article publication.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

It is permitted to use the data in other studies with reference.

From where data/document is obtainable

Dr Ala Ghazi e-mail: ghazial@mums.ac.ir

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

Sending email to authors. the authors will send data via email during 4 weeks

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Ala Ghazi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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