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 radiotheraoy. 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
دکتر محسن تفقدی
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خیابان دانشگاه، دانشگاه علوم پزشکی مشهد
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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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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