Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Improving effect of Curcumin on Chemoradiotherapy-Induced Enteritis of colorectal cancer: a randomized, double-blinded, placebo-controlled study

Protocol summary

Study aim
Ameliorative effect of curcumin on intestinal complications of colorectal cancer chemoradiation: a randomized, double-blind, placebo-controlled study.

Design
a randomized, double-blinded, placebo-controlled study in 56 patients

Settings and conduct
This double-blind, randomized clinical trial study was conducted using a placebo in the radiation therapy department of Omid Hospital in Isfahan (Seyd Al-Shahada). Random allocation was done by a third person (outside the study) and by systematic randomization. For the purpose of blinding, neither the participant in the research nor the leading researcher (physician) knew about the random allocation and drug or placebo in the capsule delivered to the patient, and only the third person (outside the study) knew the drug and placebo.

Participants/Inclusion and exclusion criteria
Rectal cancer in sage II-III which needs chemoradiation

Intervention groups
Curcumin Placebo

Main outcome variables
Decrease of bowel complications including diarrhea, bowel obstruction, abdominal pain, or blood in the stool

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220429054699N1**
Registration date: **2023-10-19, 1402/07/27**
Registration timing: **retrospective**

Last update: **2023-10-19, 1402/07/27**
Update count: **0**

Registration date
2023-10-19, 1402/07/27

Registrant information
Name
Ali Ebrahimi
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-05, 1396/01/16

Expected recruitment end date
2018-03-06, 1396/12/15

Actual recruitment start date
2017-04-05, 1396/01/16

Actual recruitment end date
2018-03-06, 1396/12/15

Trial completion date
2018-04-09, 1397/01/20

Scientific title
Improving effect of Curcumin on Chemoradiotherapy-Induced Enteritis of colorectal cancer: a randomized, double-blinded, placebo-controlled study

Public title
Improving effect of Curcumin on Chemoradiotherapy-Induced Enteritis of colorectal cancer: a randomized, double-blinded, placebo-controlled study

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Rectal cancer Indication of chemo-Radiation

Exclusion criteria:

Hypersensitivity to traumatic

Age

From **20 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **56**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Since this study is a double-blind clinical trial neither the main researcher nor the participants should know about the placement of people in the intervention and control groups. Therefore, in this study, a third person (outside the study) was asked to divide the selected people into two groups of the same size using random allocation software v.2. In this way, first, the list of people eligible to enter the study is entered into the random allocation software, the number of groups is defined for the software (2 groups, intervention, and control), and the sample size of each group is also entered (n=28). The software randomly assigns the samples to 2 groups with the same sample size, and the list of people in the two groups is kept by a third party (outside the study).

Blinding (investigator's opinion)

Double blinded

Blinding description

Since this study is double-blind, neither the main researcher nor the participants knew about the placement of the samples in the intervention categories. The intervention was done by a third person outside the study. Necessary explanations were given to them by the main researcher. The medicine capsule and placebo (formula) were completely identical in terms of size, shape and color, and only the third person (outside the study and having expertise in the field of study) knew whether it was a medicine or not. The first group (intervention) was given 500 mg curcumin daily and the control group (placebo) was given a similar capsule without medicine. Every two weeks, demographic information and clinical symptoms and signs of enterocolitis of both groups were collected by a third person and provided to the researcher.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jarib

City

Isfahan

Province

Isfehan

Postal code

8188633111

Approval date

2017-06-06, 1396/03/16

Ethics committee reference number

IR.MUI.REC.1396.3.588

Health conditions studied

1

Description of health condition studied

RECTAL CANCER

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

chemo radiation side effect

Timepoint

weekly

Method of measurement

Visiting and filling out the Criteria for Adverse Events of intestinal form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Curcumin is a medicine to reduce inflammation. In this study, we intended to measure its effect on enterocolitis caused by radiation therapy. Therefore, from the first day for 25-28 days (depending on the patients' radiotherapy time), we considered a

daily dose of 500 mg (standard curcumin capsules) for people undergoing chemotherapy. The drugs were given to the patients daily at a particular time (how many hours after chemotherapy?). This medicine was taken orally. This drug is a product of Karen Pharmaceuticals and Vital Food Supplements Company. Its ingredients include 500 mg of turmeric extract (475 mg of curcuminoids).

Category

Treatment - Drugs

2

Description

Control group: We used a capsule similar to the main drug (placebo) in the control group. This group also received a daily capsule similar to the intervention group. The treatment duration and consumption method were identical to the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
seyed al shohada hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
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Position
resident

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

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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
number of side effects
When the data will become available and for how long
of 2018
To whom data/document is available
Researchers
Under which criteria data/document could be used
all kinds of analysis
From where data/document is obtainable
Seyed alshohada Hospital
What processes are involved for a request to access data/document
The phone call is then approved by the researcher and the ethics committee
Comments