Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of curcumin on serum inflammatory cytokines and quality of life in patients with colorectal cancer under chemotrapy in comparison with placebo group

Protocol summary

Study aim
The effects of curcumin on serum concentrations of inflammatory and anti-inflammatory cytokines in patients with colorectal cancer under chemotherapy

Design
The current study is a randomized, double-blind, placebo-controlled clinical trial with parallel groups. A total of 72 subjects were recruited between April 2018 and December 2018.

Settings and conduct
Patients with colorectal cancer who referred to Baqiyatallah Oncology Clinic were enrolled in the study. All volunteers, care providers and statistician were blinded after assignment to intervention. So that, the capsules containers were coded as A and B by a non-researcher person and remained confidential until statistical analysis. The placebo capsules were similar to the drugs regarding the weight and color.

Participants/Inclusion and exclusion criteria
Patients with colorectal cancer aged more than 20 years; Colorectal cancer patients (stage 3) who have undergone surgery and need chemotherapy

Intervention groups
1) Drug: a group receiving liposomal curcumin capsules (500 mg/day) for 8 weeks, 2) Placebo: the control group who taking a placebo capsule for a period of 8 weeks.

Main outcome variables
Tumor necrosis factor alpha; Interleukin 6; Quality of life score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001165N43**
Registration date: **2020-03-13, 1398/12/23**
Registration timing: **retrospective**

Last update: **2020-03-13, 1398/12/23**
Update count: **0**

Registration date
2020-03-13, 1398/12/23

Registrant information

Name
Yunes Panahi

Name of organization / entity
Baqiyatallah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
2018-04-21, 1397/02/01

Actual recruitment end date
2018-12-31, 1397/10/10

Trial completion date
2018-12-31, 1397/10/10

Scientific title
The effects of curcumin on serum inflammatory cytokines and quality of life in patients with colorectal cancer under chemotrapy in comparison with placebo group

Public title
The Effects of Curcumin on Patients with Colorectal Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with colorectal cancer aged more than 20 years Colorectal cancer patients (stage 3) who have undergone surgery and need chemotherapy
Exclusion criteria:
Age less than 20 years Patients who need a change of the treatment
Age
From **20 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **32**
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly assigned to one of the treatment groups based on random allocation sequence generated by a statistician: 1) Drug: a group receiving liposomal curcumin capsules (500 mg/day) for 8 weeks (n=36), 2) Placebo: the control group who taking a placebo capsule for a period of 8 weeks (n=36). The tables of the Fleiss book were used to generate the random allocation sequence. The allocation scheme was consecutively numbered in envelopes which opened sequentially by an independent person, not involved in the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
All volunteers, care providers and statistician were blinded after assignment to intervention. So that, the capsules containers were coded as A and B by a non-researcher person and remained confidential until statistical analysis. The placebo capsules were similar to the drugs regarding the weight and color.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences,Tehran, Iran
Street address
Sheikh Bahaie South Street, Mulla Sadra Street, Vanak Square, Tehran, IRAN
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Province
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Postal code
1435916471
Approval date
2018-03-07, 1396/12/16
Ethics committee reference number
IR.BMSU.REC.1396.1870

Health conditions studied

1

Description of health condition studied
Colorectal cancer
ICD-10 code
C19
ICD-10 code description
Malignant neoplasm of rectosigmoid junction

Primary outcomes

1

Description
Tumor necrosis factor alpha
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

2

Description
Interleukin 6
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

3

Description
Total quality of life score
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement

Using EORTC QLQ questionnaire

Secondary outcomes

1

Description
Interleukin 1 alpha
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

2

Description
Interleukin 1 beta
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

3

Description
Interleukin 2
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

4

Description
Interleukin 4
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

5

Description
Interleukin 8
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

6

Description
Interleukin 10
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

7

Description
Monocyte chemoattractant protein
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

8

Description
Interferon gama
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

9

Description
Epidermal growth factor
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

10

Description
Vascular endothelial growth factor
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Sandwich and competitive chemiluminescence immunoassays

11

Description
Selectin
Timepoint
8 weeks after taking drug or placebo
Method of measurement
Enzyme Linked Immunosorbent Assay

12

Description

Intercellular Adhesion Molecule 1
Timepoint
8 weeks after taking drug or placebo
Method of measurement
Enzyme Linked Immunosorbent Assay

13

Description
Vascular Cell Adhesion Molecule 1
Timepoint
8 weeks after taking drug or placebo
Method of measurement
Enzyme Linked Immunosorbent Assay

14

Description
C Reactive Protein
Timepoint
Before the intervention and 8 weeks after taking drug or placebo
Method of measurement
Using Auto analyzer and Bio system Kit

Intervention groups

1

Description
Intervention group: Subjects in the intervention group receive curcumin-piperine capsules (daily intake of 500 mg curcumin plus 5 mg piperine) for 8 weeks (n=36). The participants take one capsule every day, which was contained in an unlabeled bottle. Capsules are from Sami Labs company (Bangalore, India).
Category
Treatment - Drugs

2

Description
Control group: Placebo capsules are prepared by a similar company and are similar to the curcumin capsules regarding the color, shape and size. The control group receive a placebo capsule containing lactose plus 5 mg piperine for a period of 8 weeks (n=36). The participants take one capsule every day, which was contained in an unlabeled bottle. Capsules are from Sami Labs company (Bangalore, India).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah University of Medical Sciences
Full name of responsible person
Yunes Panahi
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Sheikh Bahaie South Street, Mulla Sadra Street, Vanak Square, Tehran, IRAN
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Sponsors / Funding sources

1

Sponsor
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Bagheiat-allah University of Medical Sciences
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https://www.bmsu.ac.ir/Portal/home/?274484/bmsu-portal
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Yunes Panahi
Position
Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Raw data will be shared upon a reasonable request from the corresponding author.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Following a reasonable request, deidentified data will be shared.
When the data will become available and for how long
After publication of paper(s) upon a reasonable request
To whom data/document is available
Study PI and executive team
Under which criteria data/document could be used
For reasonable research or clinical purpose
From where data/document is obtainable
Dr. Yunes Panahi
What processes are involved for a request to access data/document
ایمیل مستقیم
Comments