Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Clinical trial for comparison of effects of curcumin and placebo on clinical severity of mild to moderate ulcerative colitis

Protocol summary

Summary

This is a randomized and double-blind clinical trial to compare the effects of curcumin and placebo on clinical features of ulcerative colitis. At least 54 patients 18-80 years old with mild to moderate ulcerative colitis (based on Simple Clinical Colitis Activity Index, from 5 to 11 scores) will be included. Patients will be randomized into two groups of curcumin (three capsules of curcumin plus three grams of mesalamine daily for 4 weeks) and placebo (three capsules of placebo plus three grams of mesalamine daily for 4 weeks). At the ends of second and fourth weeks of treatment, the clinical responses - based upon the same criteria- will be evaluated and compared as needed. Clinical side effects will also be recorded. Patients who need hospitalization, those who have significant comorbidities including liver or kidney diseases, pregnant and lactating women, as well as those with significant side effects will be excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052634142N1**
Registration date: **2017-07-01, 1396/04/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-01, 1396/04/10

Registrant information

Name

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Name of organization / entity

Iran university of medical sciences, Hazrat Rasoul Medical Complex

Country

Iran (Islamic Republic of)

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+98 21 64351

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-09-05, 1396/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial for comparison of effects of curcumin and placebo on clinical severity of mild to moderate ulcerative colitis

Public title

Effect of curcumin on ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients 18-80 years old with mild to moderate ulcerative colitis based on Simple Clinical Colitis Activity Index Exclusion criteria: hospital admission; significant comorbidities including liver or kidney diseases; pregnancy; lactating women; significant side effects during the intervention

Age

From **18 years** old to **80 years** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Iran University of Medical Sciences Campus, Hemmat freeway, next to Milad tower
City
Tehran
Postal code
Approval date
2017-01-17, 1395/10/28
Ethics committee reference number
IR.IUMS.REC 1395.9411366003

Health conditions studied

1

Description of health condition studied
Ulcerative colitis
ICD-10 code
K51
ICD-10 code description
ulcerative colitis

Primary outcomes

1

Description
The severity of ulcerative colitis
Timepoint
Before the intervention, two weeks and four weeks after the intervention onset
Method of measurement
Based on Simple Clinical Colitis Activity Index

Secondary outcomes

1

Description
Side effects
Timepoint
Two weeks and four weeks after the intervention onset and also any time patient reports during the intervention
Method of measurement
Interviews with patients

Intervention groups

1

Description
Oral curcumin as 80 mg nanomicelle capsule, three capsules per day in three divided doses before meals for 4 weeks plus standard treatment for each patient as needed which at least includes oral mesalamine tablets 500 mg, six tablets per day in three divided doses for 4 weeks.
Category
Treatment - Drugs

2

Description
Oral placebo capsule, three capsules per day in three divided doses before meals for 4 weeks plus standard treatment for each patient as needed which at least includes oral mesalamine tablets 500 mg, six tablets per day in three divided doses for 4 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Medical Complex
Full name of responsible person
Street address
Niayesh street, Sattarkhan avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology, Iran University of Medical Sciences

Full name of responsible person
Morteza Naserbakht (Manager of research & technology)
Street address
Iran University of Medical Sciences Campus, Hemmat freeway, next to Milad tower
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology, Iran 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
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Web page address

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