

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Mohammadali Mahdiabadi

Name of organization / entity

Iran university of medical sciences, Hazrat Rasoul Medical Complex

Country

Iran (Islamic Republic of)

Phone

+98 21 64351

Email address

mahdiabadi.m@iums.ac.ir

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**

Iran University of Medical Sciences

Full name of responsible person

Mohammadali Mahdiabadi

Position

Gastroenterology fellowship

Other areas of specialty/work**Street address**

Department of gastroenterology, Hazrat Rasoul Medical Complex, Niayesh street, Sattarkhan avenue

City

Tehran

Postal code**Phone**

+98 21 6651 4001

Fax**Email**

mahdiabadi.m@iums.ac.ir;
mahdiabadi1349@gmail.com;
mahdiabadi_ma@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mohsen Masoodi

Position

Associate professor of gastroenterology

Other areas of specialty/work**Street address**

Department of gastroenterology, Hazrat Rasoul Medical Complex, Niayesh street, Sattarkhan avenue

City

Tehran

Postal code**Phone**

+98 21 6651 4001

Fax**Email**

masoodi.m@iums.ac.ir; masoodi47@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mohammadali Mahdiabadi

Position

Gastroenterology fellow

Other areas of specialty/work**Street address**

Department of gastroenterology, Hazrat Rasoul Medical Complex, Niayesh street, Sattarkhan avenue

City

Tehran

Postal code**Phone**

+98 21 6651 4001

Fax**Email**

mahdiabadi.m@iums.ac.ir;
mahdiabadi1349@gmail.com;
mahdiabadi_ma@yahoo.com

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