

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of curcumin supplementation on clinical Outcomes, and some Inflammatory Markers in Patients with Ulcerative Colitis

#### Protocol summary

serum hs-CRP and TNF-a; ESR; Stool frequency per day;  
Frequency of rectal bleeding per day

#### Study aim

Determination and comparison of the effect of curcumin supplement on clinical signs and some inflammatory indices (hs-CRP and TNF-a) in patients with ulcerative colitis

#### Design

The present study is a clinical trial of phase 3, randomized, double blind and parallel, will be carried out on 70 patients with ulcerative colitis. Patients are randomly divided into two groups. The intervention group received 3 capsules of 500 mg curcumin daily for 60 days and the control group received 3 capsules of 500 mg placebo for 60 days. Demographic data; ESR; serum hs-CRP and TNF- $\alpha$ , clinical signs, physical activity, and 3-day recall recording, before and after the intervention.

#### Settings and conduct

The present study is a double-blind clinical trial with the aim of evaluating the effect of curcumin supplement on serum TNF-a and hs-CRP in patients with ulcerative colitis at Imam khomeini Hospital, Ahvaz. Physician, researcher, patient and data analyst is not aware of the type of the treatment.

#### Participants/Inclusion and exclusion criteria

The severity of the disease is mild to moderate; Patients without current diagnosis of other inflammatory and autoimmune disease; The age range is between 17-70 years; Tendency to participate in the study; The patient should not be pregnant or breastfeeding; Exclusion criteria: The patient is in the acute phase of the disease; Smoking, alcohol and drug abuse; Patients with gallstones or any disorder of the gallbladder, bladder stones.

#### Intervention groups

Intervention group: Curcumin supplement, 1500 milligram daily, 3 times per day, 500 milligram capsule each time, for 60 days. Karen Pharma Co. Control group: Placebo, Corn starch, 3 times per day, 500 milligram capsule each time, for 60 days. Karen Pharma Co.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180207038664N1**

Registration date: **2018-04-30, 1397/02/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-30, 1397/02/10**

Update count: **0**

##### Registration date

2018-04-30, 1397/02/10

##### Registrant information

##### Name

Narges Sadeghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3336 1984

##### Email address

sadeghi.n@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-19, 1396/11/30

##### Expected recruitment end date

2018-07-22, 1397/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of curcumin supplementation on clinical Outcomes, and some Inflammatory Markers in Patients with Ulcerative Colitis

**Public title**

The effect of curcumin supplementation in the treatment of patients with ulcerative colitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Ulcerative colitis, confirmed by histopathology The severity of the disease is mild to moderate Patients without current diagnosis of other inflammatory, autoimmune and inclusive disease( including cancer, kidney disease, rheumatoid arthritis, liver disease, AIDS, and cardiovascular disease) The age range is between 17-70 years Tendency to participate in the study No changes in the type and amount of drug in the past month The patient should not be pregnant or breastfeeding

**Exclusion criteria:**

The patient is in the acute phase of the disease Reluctance to continue cooperation in this research History of large gastrointestinal surgery (except appendectomy, Cholecystectomy and hemorrhoidectomy) Smoking, alcohol and drug abuse Patients with gallstones or any disorder of the gallbladder, bladder stones

**Age**

From **17 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization in this study will be done by simple method. The unit of randomization is individual. Using a random number table, a number is considered for each patient, respectively. To the number 0-4, box A and to the number 5-9, box B delivered by an individual except the researcher. So that the person providing the treatment is unaware.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The type of blindness in our study will be double-blind.

Prior to the onset of the study, the box containing the relevant capsules are coded A and B by an individual except the researcher, in order to blind the researcher about which supplement each group received. When delivering supplements to patients, some one except the researcher should locate the patient in either A or B group by random number table. In this study, the patient, physician and researcher (who collecting data, assessing the outcome and analyzing the data) should be kept blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz University of Medical Sciences

**Street address**

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Approval date**

2018-01-20, 1396/10/30

**Ethics committee reference number**

IR.AJUMS.REC.1396.895

**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**

Serum hs-CRP

**Timepoint**

The beginning of the study- The end of the study

## Method of measurement

ELISA

## 2

### Description

Serum TNF-a

### Timepoint

The beginning of the study- The end of the study

### Method of measurement

ELISA

## 3

### Description

Serum ESR

### Timepoint

The beginning of the study- The end of the study

### Method of measurement

Westergren's Method

## 4

### Description

Stool frequency per day

### Timepoint

The beginning of the study- The end of the study

### Method of measurement

Mayo Score

## 5

### Description

Frequency of rectal bleeding per day

### Timepoint

The beginning of the study- The end of the study

### Method of measurement

Mayo Score

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group:Curcumin supplement, 1500 milligram daily, 3 times per day ,500 milligram capsule each time, for 60 days. Karen Pharma & Food Supplement Co.

### Category

Treatment - Drugs

## 2

### Description

Control group: Placebo, Starch and edible color, 3 times per day ,500 milligram capsule each time, for 60 days. Karen Pharma & Food Supplement Co.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Khomeini Hospital

#### Full name of responsible person

Narges Sadeghi

#### Street address

Imam Khomeini Hospital,Azadegan Ave, Ahvaz

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

6135815751

#### Phone

+98 61 3321 4578

#### Email

sadeghi.n@ajums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Ahvaz University of Medical Sciences

#### Full name of responsible person

Mohammad Badavi

#### Street address

Vice Chancellor for Research and Technology,Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

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#### Email

badavi-m@ajums.ac.ir

#### Web page address

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Narges Sadeghi

**Position**

Msc Student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Paramedicine, Jundishapur University of Medical Sciences

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Anahita Mansoori

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data**

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Ahvaz University of Medical Sciences

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Narges Sadeghi

**Position**

Msc Student

**Latest degree**

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**Other areas of specialty/work**

Nutrition

**Street address**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

If the decision is to publicate the data, after the unidentified individuals all data will be publicated.

**When the data will become available and for how long**

The access period will be 6 months after the publication of the results.

**To whom data/document is available**

Researchers working in academic and industrial institutions can apply to get data.

**Under which criteria data/document could be used**

To cite. Referring to reference or researcher's permission

**From where data/document is obtainable**

Narges Sadeghi Faculty of Paramedicine, Jundishapur  
University of Medical Sciences, Golestan Blvd, Ahvaz.  
06133214578 sadeghi.n@ajums.ac.ir

**What processes are involved for a request to access****data/document**

Access to articles related to this research Send email to  
the responsible author

**Comments**