Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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-α, 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

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

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

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Iran (Islamic Republic of)

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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

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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
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Imam Khomeini Hospital,Azadegan Ave, Ahvaz
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Sponsors / Funding sources

1

Sponsor
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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
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

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Assistant Professor

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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