Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The efficacy of chicoridin in improvement of ulcerative colitis symptoms and patients' self-reported well-being

Protocol summary

Study aim
Effect of chicoridin on ulcerative colitis
Design
randomized case-control clinical trial with two arms parallel study design on 54 patient
Settings and conduct
This is a randomized case-control clinical trial to compare the effects of chicoridin on clinical features of ulcerative colitis of patient referred to the gastroenterology clinic of Rasoul-e-Akram Hospital in the years 2019 and 2020. Patients will be randomized into two groups of chicoridin (three capsules of curcumin plus three grams of mesalamine daily for 8 weeks) and control group (three grams of mesalamine daily for 8weeks). At the ends of 4 and 8 weeks of treatment, the clinical responses -based upon the same criteria- will be evaluated and compared as needed.
Participants/Inclusion and 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
Intervention groups
Oral chicoridin, three capsules per day in three divided doses before meals for 8 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 8 weeks.
Main outcome variables
The severity of ulcerative colitis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190712044182N2**
Registration date: **2019-12-30, 1398/10/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-30, 1398/10/09**
Update count: **0**
Registration date
2019-12-30, 1398/10/09

Registrant information
Name
Mohsen Masoodi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6655 4790
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masoodi.m@iums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-12-21, 1398/09/30
Expected recruitment end date
2020-12-21, 1399/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The efficacy of chicoridin in improvement of ulcerative colitis symptoms and patients' self-reported well-being

Public title
Effect of chicoridin 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

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

One of the randomization methods is using Excel's RANDBETWEEN function. This function allows us to generate random numbers. To produce a random number in this study with sample size 54, between two numbers 1 and 54 use the = Randbetween function (1,54). This function creates a column of random numbers between 1 and 54. The rand () function selects numbers with equal probability in this interval, so the chance of choosing any number in this interval is equal to the other numbers. This means that each patient is assigned to one of two treatments, respectively. These data are 54 patients randomly assigned to two treatments, 1 and 2 (27 patients each). The sample numbers in the first and second groups are as follows: (15, 6,37,41, 23, 43, 13,35,10, 12,51,28,4,17, 26,38,20,33,11, 48, 36, 39.49, 47.8 34.22) (30, 52,27,19,42,18,9,24,40,53,1, 44, 2, 50, 45, 46,3,7,32,25, 31,54,21, 14,29 16, 5)

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemat highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.IUMS.REC.1397.1188

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 efficacy of chicoridin in improvement of ulcerative colitis symptoms and patients' self-reported well-being according to the “Simple Clinical Colitis Activity Index” (SCCAI)

Timepoint

4weeks and 8 weeks after the intervention onset

Method of measurement

Interviews with patients and complete table of “Simple Clinical Colitis Activity Index” (SCCAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral chicoridin, three capsules per day in three divided doses before meals for 8 weeks plus standard treatment for each patient as needed which at least includes oral mesalamine tablets.

Category

Treatment - Drugs

2

Description

Control group: Standard treatment for each patient including at least oral mesalamine tablets.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Colorectal Research Center

Full name of responsible person
Mohsen Masoodi

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Rasoul-e-Akram Hospital, Maziar Mansouri Ave., Sattarkhan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

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Dr Seedabas Motavalian

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Iran University of Medical Sciences, Next to Milad Tower, Hemat Highway

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mohsen Masoodi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Information about the main consequences will be shared.

When the data will become available and for how long

Start the access period, 6 months after publication of results

To whom data/document is available

Physicians , patients with ulcerative colitis

Under which criteria data/document could be used

Published as an article

From where data/document is obtainable

mohsen masoodi masoodi47@yahoo.com

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

mail will be sent to the main author or co-response, and in less than 2 week, the available data will send to the individual.

Comments