

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the combined effect of mesalazine-crocin with mesalazine alone in the treatment of inflammatory bowel disease

Protocol summary

Study aim

- Determination and comparison of clinical symptoms in patients with colitis receiving mesalazine with crocin and mesalazine alone before and after the study - Determination and comparison of parameters (AST, Calprotectin, S/E, ESR, CBCdiff, CRP, Alt, Alp.) in patients with colitis receiving mesalazine with crocin and mesalazine alone before and after the study - Determination and comparison of clinical symptoms in Crohn's patients receiving mesalazine with crocin and mesalazine alone before and after the study - Determination and comparison of parameters (AST, Calprotectin, S/E, ESR, CBCdiff, CRP, Alt, Alp.) in Crohn's patients receiving mesalazine with crocin and mesalazine alone before and after the study

Design

A controlled, single-blind, randomized, phase 3 clinical trial on 40 patients. Randomization allocation role was used for randomization.

Settings and conduct

This single-blind clinical trial study will be conducted in Hajar Hospital and Imam Ali Clinic in 1402.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Suffering from inflammatory bowel diseases, including Crohn or ulcerative colitis 2- Informed consent to participate in the study 3- Not having a history of underlying diseases and other autoimmune diseases 4- Not using other medicinal plants Exclusion criteria 1- Unwillingness to continue participating in the study 2- Pregnancy or breastfeeding 3- In case of any unwanted side effects

Intervention groups

The intervention group: standard treatment of mesalazine tablets 1000 mg plus crocin capsule 15 mg
The control group: standard treatment plus placebo

Main outcome variables

Clinical symptoms of Crohn's and colitis patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230511058153N1**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Ghorbanali Rahimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-15, 1402/03/25

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the combined effect of mesalazine-crocin with mesalazine alone in the treatment of inflammatory bowel disease

Public title

The combined effect of mesalazine-crocin in the treatment of inflammatory bowel disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inflammatory bowel diseases including Crohn's or ulcerative colitis
Informed consent to participate in the study
No history of other autoimmune diseases
No history of underlying diseases
No use of other medicinal plants
Patients with moderate type Inflammatory bowel diseases
Insensitivity to salicylates
Insensitivity to any of the saffron compounds

Exclusion criteria:

Reluctance to continue participating in the study
Death of the patient
Pregnancy or breastfeeding
In case of any unwanted side effects

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to two groups A and B using the Random Allocation Rule. 20 A cards for the intervention group and 20 B cards for the control group are placed in the lottery container. Cards are drawn randomly without replacement to create the desired sequence. And this process remains hidden from the researchers until the interventions are determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be Single blind. In such a way that only the patient is undemanding to which group he has been assigned, and the placebo capsule will be completely similar to the crocin capsule in terms of its shape and appearance.

Placebo

Used

Assignment

Parallel

Other design features

In this study, the participants will be assigned to two groups A and B using the Random Allocation Rule method, and the number of ulcerative colitis and Crohn's patients will be equalized in the grouping. Group A (intervention group) will receive crocin capsules 15 mg twice a day in addition to the standard treatment

(mesalazine 1000 mg tablets 3 times a day) and group B (control group) will receive the standard treatment plus placebo (in the form of crocin capsules) the same pharmaceutical company) will receive for 8 weeks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahrekord University of Medical Sciences

Street address

Nurse St. - Hajar Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2022-10-12, 1401/07/20

Ethics committee reference number

IR.SKUMS.MED.REC.1401.046

Health conditions studied

1

Description of health condition studied

Crohn's disease

ICD-10 code

K50

ICD-10 code description

Crohn's disease [regional enteritis]

2

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

The score of clinical symptoms of colitis in the Partial Mayo score questionnaire

Timepoint

Before the start of the intervention and 8 weeks after the start of the intervention

Method of measurement

Partial Mayo score questionnaire

2

Description

The score of the clinical symptoms of Crohn in the Harvey Bradshaw index questionnaire

Timepoint

Before the start of the intervention and 8 weeks after the start of the intervention

Method of measurement

Harvey Bradshaw index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Standard treatment (Mesalazine tablet 1000 mg 3 times a day, Kimidaro Pharmaceutical Company) plus crocin capsule 15 mg (Darumed Pharmaceutical Company) twice a day for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Standard treatment (mesalazine tablets 1000 mg 3 times a day, Kimidaro pharmaceutical company) plus placebo (in the form of crocin capsules and manufactured by the same Darumed pharmaceutical company) for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital and Imam Ali Clinic

Full name of responsible person

Ghorbanali Rahimian

Street address

Nurse St. - Hajar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Raeisi

Street address

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Ghorbanali Rahimian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ghorbanali Rahimian

Position

Associate professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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