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)

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+98 38 3222 0016

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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
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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
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Nurse Street, Hajar Hospital
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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

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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