Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Investigating the effect of crocin on metabolic indices, inflammatory biomarkers and oxidative stress factors in ulcerative colitis patients.

Protocol summary

Study aim

Investigating the effect of crocin on metabolic indices, inflammatory biomarkers and oxidative stress factors in ulcerative colitis patients receiving crocin compared with the group receiving placebo before and after the study.

Design

A crossover clinical trial with placebo control group by parallel groups, double-blind, randomized, phase 3 on 60 patients. SPSS software was used for randomization.

Settings and conduct

Place of study: Porcine Hakim, Gastrointestinal and Liver Diseases Clinic, Isfahan; Study population: Adults with ulcerative colitis 18 to 65 years; Type of blinding: Double-blind including patients and researchers; Method of blinding: Through codes designed with SPSS by a third party

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ulcerative colitis proven through clinical diagnosis and previous colonoscopy results with mild-to-moderate colitis; positive Calprotectin; Adult patients from 18 years to 65 years; No use of other medicinal plants in the past 3 months; No allergy to saffron plant and its derivatives; Not taking new antidepressants and sleeping pills in the last 2 months; No use of new anti-inflammatory and antioxidant drugs in the last 3 months; Taking the usual medications prescribed by the doctor in the last 4 months. Exclusion criteria: Normal calprotectin ; Pregnancy or breastfeeding; In case of any side effects; Anticoagulant and warfarin use; A history of other underlying diseases and autoimmune diseases; alcohol consumption.

Intervention groups

Intervention group: recipient of mesalamine with 15 mg of crocin twice daily Control group: receiving mesalamine with placebo containing starch twice a day

Main outcome variables

(calprotectin، NO،CRP، MPO،TNFα،IL-6،IL-1ß)؛(MDA،CAT، TAC, TOS,GSH)؛ (AMPK، SIRT-1، GLUT1، PKM2)؛TG-CHOL-HDL-LDL؛CBCdiff؛Clinical symptoms;The fatty acid profile of RBC membranes;MCP-1;FBS;ALT,AST,ALP

General information

Reason for update

Changes to the study design and the addition of a measurable outcome variable

Acronym

IRCT registration information

IRCT registration number: **IRCT20240831062917N1**
Registration date: **2024-09-11, 1403/06/21**
Registration timing: **prospective**

Last update: **2026-10-28, 1405/08/06**
Update count: **1**

Registration date

2024-09-11, 1403/06/21

Registrant information

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Shima Kabiri Arani
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-02-18, 1403/11/30

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of crocin on metabolic indices, inflammatory biomarkers and oxidative stress factors in ulcerative colitis patients.

Public title
Investigating the effect of crocin in ulcerative colitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ulcerative colitis proven through clinical diagnosis and previous colonoscopy results with mild-to-moderate colitis positive Calprotectin and receiving standard treatment of mesalamine Adult patients from 18 years to 65 years. No use of other medicinal plants in the past 3 months. No allergy to saffron plant and its derivatives. Not taking new antidepressants and sleeping pills in the last 2 months. No use of new anti-inflammatory and antioxidant drugs in the last 3 months. Taking the usual medications prescribed by the doctor in the last 4 months.
Exclusion criteria:
Normal calprotectin Pregnancy or breastfeeding. In case of any side effects. Anticoagulant and warfarin use. A history of other underlying diseases and autoimmune diseases. alcohol consumption Taking any anti-depressant, anti-inflammatory and new sleep medications in the last 2 months. Consumption of new anti-inflammatory and antioxidant drugs in the last 3 months. Change in commonly prescribed medications in the last 4 months.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **4**
According to the 2×2 crossover design, each participant will undergo two consecutive treatment periods, with a 3-week washout period between the two periods. In each period, two samples will be collected: one before the intervention (Baseline) and one after the intervention (Post-treatment). Therefore, a total of 4 samples will be collected from each individual (2 periods × 2 samples per period).

Randomization (investigator's opinion)
Randomized
Randomization description
30 patients with ulcerative colitis who are under standard treatment with mesalamine are selected. Randomization of samples is based on block randomization method. For random assignment with random numbers generated by SPSS software (use of random blocks with a volume of 6), each patient is assigned a code and then according to the treatment group assigned to the corresponding code, the patient is in one of the intervention groups to receive crocin or The control received a placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to conduct this research in a double-blind manner, patients, researchers, clinical caregivers, outcome assessors, and data analysts are blinded by codes designed with SPSS by a third party (a person other than the researchers). Statistical software codes consist of Latin letters A and B along with numbers. The third party assigns one of the letters A and B included in the designed codes to the crocin group and the other to the placebo group. The codes are pasted on the cans containing crocin or placebo, and based on the code written on it, it is filled by the mentioned person and given to the researcher. Finally, without knowing the contents of the cans, the researcher randomly provides them to the patients.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committees of schools of Pharmacy and Nutrition, Isfahan University of Medical Scien
Street address
Building No. 4,Research and Technology Vice President ,Isfahan University of Medical Sciences, Hazar Jarib Ave, Azadi SQ
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Isfehan
Postal code
81746-73461
Approval date
2024-07-31, 1403/05/10
Ethics committee reference number
IR.MUI.PHANUT.REC.1403.059

2

Ethics committee

Name of ethics committee

Research Ethics committees of schools of Pharmacy and Nutrition, Isfahan University of Medical Scien

Street address

Building No. 4,Research and Technology Vice President ,Isfahan University of Medical Sciences, Hazar Jarib Ave, Azadi SQ

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Isfahan

Province

Isfehan

Postal code

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Approval date

2025-06-07, 1404/03/17

Ethics committee reference number

IR.MUI.PHANUT.REC.1404.027

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

Calprotectin

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

ELISA

2

Description

Nitric oxide (NO)

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Spectrophotometry

3

Description

Myeloperoxidase (MPO)

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Spectrophotometry

4

Description

Quantitative CRP

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Turbidimetry

5

Description

Catalase

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Spectrophotometry

6

Description

Malondialdehyde (MDA)

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Spectrophotometry

7

Description

Total antioxidant capacity (TAC)

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Spectrophotometry

8

Description

AMPK gen expression

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Real-time PCR

9

Description

SIRT-1 gen expression

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Real-time PCR

10

Description

GLUT1 gen expression

Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Real-time PCR

11

Description
PKM2 gen expression
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Real-time PCR

12

Description
TNFα
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
ELISA

13

Description
IL-6
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
ELISA

14

Description
IL-1ß
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
ELISA

15

Description
Ulcerative colitis disease activity index
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Truelove and Witts' classification

16

Description
Cell Blood Count. diff.
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Hematology cell counter

Secondary outcomes

1

Description
Quality of life in ulcerative colitis
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
32-question IBD Quality of life questionnaire (IBD Q-32)

2

Description
Triglycerides (TG)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
spectrophotometry

3

Description
Total cholesterol
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
spectrophotometry

4

Description
HDL-Cholesterols
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
spectrophotometry

5

Description
LDL-Cholesterol
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Spectrophotometry

6

Description
The fatty acid profile of erythrocyte membranes
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement

Gas Chromatography

7

Description
Monocyte Chemoattractant Protein-1 (MCP-1)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
ELISA

8

Description
Total Oxidant Capacity (TOS)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Spectrophotometry

9

Description
Glutathione(GSH)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Spectrophotometry

10

Description
Fasting Blood Sugar (FBS)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Spectrophotometry

11

Description
Alanine Aminotransferase (ALT)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic kit

12

Description
Aspartate Aminotransferase (AST)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic kit

13

Description
Alkaline phosphatase (ALP)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Patients receiving the standard treatment of mesalamine plus two daily capsules of crocin (Samisaz company) for 12 weeks, orally, each containing 15 mg of crocin supplement.
Category
Treatment - Drugs

2

Description
Control group: Patients receiving standard treatment of mesalamine plus two placebo capsules containing starch daily for 12 weeks. The placebo will be completely similar to the crocin supplement in terms of shape and appearance of the package. Following a 21-day (3-week) wash-out period during which crocin and placebo are discontinued, the treatments are crossed over: the group previously receiving crocin is administered placebo, and the group previously receiving placebo is administered crocin.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Hakim Digestive Disease Research Center
Full name of responsible person
Dr. Seyed Mohammad Hassan Emami
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Building No. 4,Research and Technology Vice President ,Isfahan University of Medical Sciences, Hazar Jarib Ave.
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Postal code
81746-73461
Phone
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Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
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Full name of responsible person
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable