

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of metformin as an adjunct therapy in mild-to-moderate ulcerative colitis

Protocol summary

Study aim

Determining the effect of metformin as an adjunct therapy in mild to moderate ulcerative colitis

Design

The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized

Settings and conduct

This study will be performed to evaluate the effect of metformin on disease activity index in patients with ulcerative colitis in the clinic of Heshmatieh Hospital in Sabzevar. The outcome assessor and participants will be unaware of how the grouping works. Patients will be randomly assigned to the intervention (metformin) and control (placebo) groups. Outcome evaluation is performed using the disease activity index at the end of the second month after the intervention for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ulcerative colitis that affects at least the rectosigmoid area and its activity is confirmed by colonoscopy at the beginning of the study. Patients with ulcerative colitis over the age of 18 Patients with mild to moderate recurrent ulcerative colitis with a disease activity index of 3 to 8 points with symptoms (recurrent episodes) for less than 4 weeks before the study Exclusion criteria: Patients with Crohn's disease, diabetes, heart failure and severe renal or hepatic insufficiency, pregnant or lactating women, patients with a history of previous allergy to metformin, patients treated with systemic corticosteroids.

Intervention groups

Intervention group: Using metformin 1000 mg tablets (produced by Tehran Shimi Company) after breakfast and evening meals for two months. Control group: Using placebo tablets (prepared in Iran Pharmacy Laboratory) after breakfast and evening meals for two months.

Main outcome variables

Determining the disease activity index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041252N20**

Registration date: **2023-11-10, 1402/08/19**

Registration timing: **retrospective**

Last update: **2023-11-10, 1402/08/19**

Update count: **0**

Registration date

2023-11-10, 1402/08/19

Registrant information

Name

Mohammad Sahebkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 8337

Email address

sahebkar@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-24, 1396/02/04

Expected recruitment end date

2022-03-05, 1400/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of metformin as an adjunct therapy in mild-to-moderate ulcerative colitis	
Public title	Metformin as an adjunct therapy in mild-to-moderate ulcerative colitis
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Patients have ulcerative colitis involving at least the rectosigmoid region with the activity confirmed by colonoscopy at the beginning of the study Patients with ulcerative colitis over 18 years of age Patients with mild to moderate recurrent ulcerative colitis with a disease activity index of 3 to 8 points with symptoms (recurrent episodes) for less than 4 weeks before the study Exclusion criteria: Patients with Crohn's disease, diabetic mellitus, heart failure, and severe renal or hepatic failure. Pregnant or lactating women Patients with mild to moderate recurrent ulcerative colitis with a disease activity index of less than 3 and more than 8 points with symptoms (recurrent episodes) for less than 4 weeks before the study Patients with a past history of allergy to metformin Patients treated with systemic corticosteroids, anti-tumor necrosis factor (TNF) or cyclosporine in the last 8 weeks and during the study period Patients with any changes in the oral dose of 5-ASA or 6-mercaptopurine and azathioprine in the last 12 weeks and during the study. In addition, patients taking rectal 5-ASA or steroids 4 weeks before enrollment or during the 8-week study period.
Age	From 18 years old to 55 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 84
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization is based on permutation blocks. Accordingly, 21 blocks are allocated to patients, in each block 2 from the treatment group and 2 from the B treatment group are placed. Eventually, after completion of the blocks, after blocks are completed, group A is treated with metformin 1000 mg tablets, and group B is treated with placebo tablets.
Blinding (investigator's opinion)	Double blinded
Blinding description	Each person in the study will be assigned codes A and B, and the researcher will only be known of the type of group. The outcome evaluator and participants are unaware of the groups. It should be noted that metformin and placebo are similar in appearance, color, and packaging.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics committee of Sabzevar University of Medical Sciences Street address Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city City Sabzevar Province Razavi Khorasan Postal code 9617913114 Approval date 2016-10-04, 1395/07/13 Ethics committee reference number IR.MEDASB.REC.1395.80
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 Determining disease activity index (DAI) Timepoint Before the intervention and two months after the intervention Method of measurement Mayo Score/Disease Activity Index (DAI) for Ulcerative Colitis
Secondary outcomes	empty

Intervention groups

1

Description

Intervention group: Patients in this group consume 1000 mg metformin tablet (produced by Tehran Shimi Company) for two months after breakfast and evening meals.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group consume placebo tablets (prepared in the Iranian Pharmacy Laboratory) for two months after breakfast and evening meals.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatiyeh hospital

Full name of responsible person

Mahdi Molavi

Street address

Heshmatiyeh Hospital, Asadabady Ave., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 915 317 3029

Email

molavi.m@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Hossein Saghi

Street address

Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 8319

Email

saghi9@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mahdi Molavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Heshmatiyeh Hospital, Asadabady Ave., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1014

Email

molavi.m@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mahdi Molavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Heshamatiyeh Hospital, Asadabady Ave., Sabzevar
Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1014

Email

molavi.m@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Sahebkar

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

Heshamatiyeh Hospital, Asadabady Ave., Sabzevar
Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1014

Email

Mohammad.sahebkar66@yahoo.com

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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available