Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 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
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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
Heshamatiyeh Hospital, Asadabady Ave., Sabzevar Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
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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
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
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Assistant 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
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