

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

To investigate the therapeutic potency of Mebendazole in combination with standard treatment, mesalamine, in Ulcerative colitis patients

Protocol summary

Study aim

To investigate therapeutic potency of Mebendazole in decreasing ulcerative colitis clinical symptoms

Design

This is a phase III randomized, parallel, double blinded, clinical trial with 54 participants divided into Standard versus Mebendazole-treated groups.

Settings and conduct

This is a clinical study on Therapeutic potency of Mebendazole in Ulcerative colitis which will be performed in Mashhad University of Medical Sciences Hospitals This is a double-blinded study in which both participants and data collectors will be blind to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Informed consent 2. 18 to 60 years. 3. Moderate proctosigmoiditis and Left-sided colitis. 4. With no active gastrointestinal infection. Exclusion Criteria: 1. Subjects with Crohn's disease or other types of colitis including Infectious, Radiation or Ischemic colitis. 2. Allergy to Mesalamine or Mebendazole. 3. Subjects who have a positive pregnancy test, or breast feeding. 4. Subjects treated with immuno-modulatory drugs from two months before screening or receiving pro- or antibiotics from two weeks from screening. 5. Patients who have already received metronidazole or Mebendazole for parasitic worm infection. 6. patients with leukopenia, thrombocytopenia, neutropenia or Hb< 10. 7. Subjects with Chronic Medical Conditions including heart diseases, lung diseases esp. Tuberculosis, Renal dysfunction, liver diseases, coagulation disorders, Drug abuse 8. Patients with Ulcerative Proctitis.

Intervention groups

Ulcerative colitis patients in the intervention group will receive Mesalazine as standard treatment (3g/daily) combined with 300 mg/daily of Mebendazole orally.

Main outcome variables

Clinical Symptoms including weight loss, fever, bowel movement frequency, Stool consistency, Presence or absence of blood in feces, Mucus in feces will be

investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220115053713N2**

Registration date: **2022-04-16, 1401/01/27**

Registration timing: **prospective**

Last update: **2022-04-16, 1401/01/27**

Update count: **0**

Registration date

2022-04-16, 1401/01/27

Registrant information

Name

Seyed Mahdi Hasanian Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 203 0439

Email address

hasanianmehr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To investigate the therapeutic potency of Mebendazole in combination with standard treatment, mesalamine, in Ulcerative colitis patients

Public title

Mebendazole in combination with mesalamine against Ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Provide written documentation of informed consent to participate in the study. Male or female aged 18 to 60 years. Subjects with a confirmed diagnosis of moderate proctosigmoiditis and Left-sided colitis. Diagnosis established by endoscopy and histology. Participants have no proven current active gastrointestinal infection.

Exclusion criteria:

Subjects with Crohn's disease or other types of colitis including Infectious, Radiation or Ischemic colitis. Allergy to Mesalamine or Mebendazole. Subjects who have a positive pregnancy test, or breast feeding. Subjects treated with immuno-modulatory drugs from two months before screening or receiving pro- or antibiotics from two weeks from screening. Patients who have already received metronidazole or Mebendazole for parasitic worm infection. Subjects with leukopenia, thrombocytopenia, neutropenia, Hb < 10 Subjects with Chronic Medical Conditions including heart diseases, lung diseases esp. Tuberculosis, Renal dysfunction, liver diseases, coagulation disorders, Drug abuse Patients with Ulcerative Proctitis.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

It is a Block randomized trial in which the Random Allocation Software will be used for allocation concealment which is performed according to SNOSE (sequentially numbered, opaque, sealed envelopes) technique. Envelopes will be sealed and one of the executive member will put randomized number into pockets. Following providing written documentation of informed consent to participate the subjects will pick up a pocket which will be divided into control or intervention group accordingly. Size of Blocks will be four in the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind clinical trial in which participants and data analyzers will be blinded to the study. In this randomized controlled trial blinding is achieved with placebo. Compared to the treatment, placebo will have the same shape and color. Since double-blinded studies are considered valid approach in decreasing bias in clinical trials, both participants and data analyzers are blinded in this study. It is worth mentioning that participants are aware that they might be randomly categorized either in the treatment or control group. The principal investigator is responsible for the safety of the project, assessing results, and writing the manuscript. He is not blinded to final outcomes. Data collectors, Data analyzers will be blinded in this study. Data Safety and Monitoring Board are not blind to data.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Medical School, Mashhad University of Medical Sciences

Street address

Medical School, Mashhad University of Medical Sciences, University campus, Azadi Square, Mashhad, Razavi Khorasan, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2021-11-30, 1400/09/09

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.625

Health conditions studied

1

Description of health condition studied

Ulcerative (chronic) rectosigmoiditis

ICD-10 code

K51.3

ICD-10 code description

Ulcerative (chronic) rectosigmoiditis

2

Description of health condition studied

Left sided colitis, left hemicolitis

ICD-10 code

K51.5

ICD-10 code description

Left sided colitis

Primary outcomes

1

Description

Clinical Symptoms including weight loss, fever, bowel movement frequency, Stool consistency, Presence or absence of blood in feces, Mucus in feces

Timepoint

Before intervention, 1, 2 and 3 months after intervention

Method of measurement

Will be evaluated by physician

Secondary outcomes

1

Description

Laboratory Findings including measurement of Aspartate transaminase, Alanine transaminase, Alkaline phosphatase, total and direct bilirubin, albumin, urea, creatinine, sodium, potassium, complete blood count, prothrombin time, partial thromboplastin time, international normalized ratio, total iron-binding capacity, iron, erythrocyte sedimentation rate, C-reactive protein, fecal calprotectin, and stool culture.

Timepoint

Before intervention, 1, 2 and 3 months after intervention

Method of measurement

Standard laboratory methods

2

Description

Histological findings including functional and cytological changes in crypts, presence of Paneth cells, alterations in mucus and sub-mucus, presence of crypt abscess, Cryptitis, reduction in intraepithelial muscins, presence of eosinophils in lamina propria, Basal Plasmacytosis and basal lymphoid aggregates.

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Histology

Intervention groups

1

Description

Intervention group: Ulcerative colitis patients in the intervention group will receive Mesalazine as standard treatment (3g/daily) combined with 300 mg/daily of

Mebendazole orally.

Category

Treatment - Drugs

2

Description

Control group: This group will receive Mesalazine as standard treatment (3g/daily) plus placebo of Mebendazole.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences, Imam Reza Hospital

Full name of responsible person

Seyed Mahdi Hassanian Mehr

Street address

Ebne Sina St. Taghiabad Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

hasanianmehrm@mums.ac.ir

Web page address

2

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences, Ghaem Hospital

Full name of responsible person

Seyed Mahdi Hassanian Mehr

Street address

Ahmadabad St. Taghiabad Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9187145785

Phone

+98 51 3840 0000

Email

hasanianmehrm@mums.ac.ir

Sponsors / Funding sources

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour-Mobarhan

Street address

Azadi Sq. Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9197985174

Phone

+98 51 3841 2081

Email

GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Mahdi Hassanian Mehr

Position

Associate Proffessor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9197985174

Phone

+98 51 3800 2353

Fax

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Mahdi Hassanian Mehr

Position

Associate Proffessor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9197985174

Phone

+98 51 3800 2353

Fax

Email

hasanianmehrm@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Mahdi Hassanian Mehr

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3800 2353

Fax

Email

hasanianmehrm@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
We will be ready to share all the collected de-identified participant data (IPD) to other researchers after the end of study.
When the data will become available and for how long
Sharing of all collected de-identified participants data (IPD) will be started immediately after publication.
To whom data/document is available
All collected de-identified participants data (IPD) will be

shared to people working either in academic institutions or business companies upon their request.
Under which criteria data/document could be used
The collected de-identified participants data (IPD) will be only shared to those recipients who commit themselves to use them only for patients. They also should commit themselves to share these data with other organization only after asking permission from the original source.
From where data/document is obtainable
Data/Documents will be obtainable by sending an e-mail to hasanianmehr@ums.ac.ir
What processes are involved for a request to access data/document
The applicant who wish to have access to document/data files should send an e-mail to hasanianmehr@ums.ac.ir commit him/herself to not to share these documents with others unless asking permission from the original source. Next, document/data will be sent to him/her by e-mail immediately.
Comments