Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 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
hasanianmehrm@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, plecebo 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.
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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
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Sponsors / Funding sources

1

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
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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
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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Mahdi Hasanian Mehr
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Associate Professor
Latest degree
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Other areas of specialty/work
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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 paticipant 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 hasanianmehrm@mums.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 hasanianmehrm@mums.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