Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of Sodium Pentaborate Enema on Left Side Ulcerative Colitis Clinical Signs and Colonoscopic Findings

Protocol summary

Study aim
Effect of saffron solution enema on Ulcerative colitis activity

Design
Randomized double blinded Clinical Trial, Phase 3 on 60 patients. Randomized by GraphPad Software.

Settings and conduct
The study will take place at GI Clinics of Medicine Faculty of Tabriz University of Medical sciences. Patients in the control group are prescribed mesalazine 2 g daily and an enema gel without Sodium Pentaborate as a placebo in the amount of 100 cc daily for 4 weeks. The intervention group is prescribed 2 grams of mesalazine daily and a Sodium Pentaborate 3% enema gel in the amount of 100cc daily for 4 weeks. Random assignment of patients into two groups is done using simple random method using codes by Graphpad software. The drug and placebo codes are received using this software and specified as solutions A and B. The random numbers and codes will only be available to the head nurse and the patients and the specialist and the statistical analyst will be blind to the allocation of people to the study groups. Drugs and placebo are similar in shape, color, and appearance.

Participants/Inclusion and exclusion criteria
Patients between 18 and 65 years old with newly diagnosed left side ulcerative colitis who can endure enema

Intervention groups
In this randomized, double-blind study, 60 patients with left side ulcerative colitis whom are selected by available sampling and entered the study are going to be randomly divided into two groups. Patients in the control group are prescribed Iranian mesalazine 2 g daily and an enema gel without Sodium Pentaborate as a placebo in the amount of 100 cc daily for 4 weeks. The intervention group is prescribed 2 grams of mesalazine daily and a Sodium Pentaborate 3% enema gel in the amount of 100cc daily for 4 weeks.

Main outcome variables
The primary outcome in this study is the severity of the activity of the disease, which will be measured using the mayo score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190701044062N11**
Registration date: **2022-09-08, 1401/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-08, 1401/06/17**
Update count: **0**

Registration date
2022-09-08, 1401/06/17

Registrant information

Name
manouchehr khoshbaten

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 1334 3010

Email address
mkhoshbaten@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Sodium Pentaborate Enema on Left Side Ulcerative Colitis Clinical Signs and Colonoscopic Findings

Public title
Evaluation of Sodium Pentaborate on Left Side Ulcerative Colitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All left side ulcerative colitis patients who are between 18 and 65 years old
Exclusion criteria:
Patients who can't endure enema Patients with other diseases as : Crohn's disease, Intermediate Colitis, CMV, Pseudomemberanous Colitis, Heart Failure, CRF, PSC Pregnant or breastfeeding patients
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of patients to two groups is done using the simple randomization method using the codes provided by Graphpad software. The drug and placebo codes are also received using this software and specified as solutions A and B, and then will be presented to the patients by the secretary. Until the end of the study, random numbers and codes will only be available to the supervisor head nurse who is not present in other parts of the study. The patients, the secretary providing the drugs, the specialist evaluating the severity of the disease, and the statistical analyst are blinded to the allocation of people to the study groups until the end of the study, and thus concealment is done in randomization.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and specialists evaluating the severity of the disease and the statistical analyst will be blind to the allocation of individuals to study groups until the end of the study. Design, color, appearance and all other properties of drug and placebo are same for blinding the study for individuals too.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
The central building of Tabriz University of Medical Science,Golgasht St.,Azadi St.
City
Tabriz
Province
East Azarbaijan
Postal code
5154751637
Approval date
2021-11-23, 1400/09/02
Ethics committee reference number
IR.TBZMED.REC.1400.788

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
Activity of disease based on Mayo score
Timepoint
Assessment of disease activity at the beginning of the study and 28 days after the start of using Sodium Pentaborate enema
Method of measurement
Mayo Score

Secondary outcomes

1

Description
Frequency of daily defecation
Timepoint
Assessment of daily defecation frequency at the beginning of the study and 28 days after the start of using Sodium Pentaborate enema
Method of measurement
By asking the patient about frequency of daily defecation and using it in Mayo Score scale

2

Description
Rectal Bleeding
Timepoint
Assessment of rectal bleeding at the beginning of the study and 28 days after the start of using Sodium Pentaborate enema
Method of measurement
By asking the patient about frequency and amount of of rectal bleeding and using it in Mayo Score scale

3

Description
Endoscopic findings
Timepoint
Assessment of endoscopic findings at the beginning of the study and 28 days after the start of using Sodium Pentaborate enema
Method of measurement
By direct vision of endoscopist based on Endoscopic Sub Score in Mayo Score scale

Intervention groups

1

Description
Intervention group: Patients in the intervention group are prescribed 2 grams of Oral tablet of mesalazine daily and a Sodium Pentaborate 3% rectal enema gel(Satin Tan Kimia company product) in the amount of 100cc daily for 4 weeks. Also at the beginning of the trial for each patient, a training class will be held to train the patient about the process of study.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group are prescribed Oral tablet of mesalazine 2 g daily and a rectal enema gel without Sodium Pentaborate as a placebo(Satin Tan Kimia company product) in the amount of 100 cc daily for 4 weeks. Also at the beginning of the trial for each patient, a training class will be held to train the patient about the process of study.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Medical Research and Training Hospital
Full name of responsible person
Manouchehr Khoshbaten
Street address
Imam Reza Hospital Clinic, Golgasht St.
City
Tabriz
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+98 41 3337 2088
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mkhoshbaten@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ata Mahmoodpour
Street address
Imam Reza Hospital Clinic, Golgasht St.
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a.mahmoodpour@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Manouchehr Khoshbaten

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Imam Reza Hospital Clinic, Golgasht St.

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Professor

Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

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