

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,
Pseudomembranous 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.

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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

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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

mkhoshbaten@yahoo.com

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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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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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