Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison between topical 5-ASA versus combined oral and topical 5-ASA for the treatment of ulcerative proctitis.

Protocol summary

Study aim
Comparison between combined oral and topical 5-ASA versus topical 5-ASA for the treatment of ulcerative proctitis

Design
Clinical trial without control group, with parallel groups, triple-blinded, randomized, phase 2 on 64 patients. Block method was used for randomization.

Settings and conduct
In this study, all patients over 15 years of age referred to Amir al-Momenin Hospital in Arak with the diagnosis of ulcerative colitis in colonoscopy and histopathology and relevant tests are included in the study. The patients of the first group were given mesalazine suppositories, and the patients of the second group were given oral mesalazine along with mesalazine suppositories, and the patients were followed up for 6 months. Finally, laboratory criteria, severity of disease activity and response to treatment are examined in two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: people over 15 years of age who have been diagnosed with ulcerative proctitis through colonoscopy and histology at Amirul Mominin Hospital in Arak during 1398-1402 Exclusion criteria: patients with sensitivity to salicylate, active peptic disease, proven coagulation problem, significant liver, kidney or heart disease, pregnant or lactating women, as well as patients whose previous treatment with 5-ASA has not been effective or undergoing maintenance treatment with compounds 5 -ASA.

Intervention groups
The first intervention group: patients treated with mesalazine suppositories at the rate of one gram per day for 6 months The second intervention group: patients treated with oral mesalazine at the rate of 3 grams per day along with mesalazine suppositories of 1 gram per day for 6 months.

Main outcome variables
Severity of disease activity, response to treatment and laboratory criteria

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231029059892N1**
Registration date: **2023-11-20, 1402/08/29**
Registration timing: **prospective**

Last update: **2023-11-20, 1402/08/29**
Update count: **0**

Registration date
2023-11-20, 1402/08/29

Registrant information

Name
Esmaeil Mirshafiee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3836 0000

Email address
esmaeilmirshafiee@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-21, 1402/08/30

Expected recruitment end date
2024-04-29, 1403/02/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison between topical 5-ASA versus combined oral and topical 5-ASA for the treatment of ulcerative proctitis.

Public title
Comparison between combined oral and topical 5-ASA versus topical 5-ASA on ulcerative proctitis.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All people who have been diagnosed with ulcerative proctitis through colonoscopy and histology during the years 1398-1402. Patients over 15 years old

Exclusion criteria:
Patients with salicylate allergy Active peptic disease A proven coagulation problem Pregnant and lactating women Significant liver and kidney disease

Age
From **15 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization has been done based on the 6 permutation block method taken from Randomization.org and the patients have been divided into two groups A (local treatment) and B (local and oral combination).

Blinding (investigator's opinion)
Triple blinded

Blinding description
The study is a triple-blind type. The patients do not know about the assignment of the groups, and the doctor and also the data analyst do not know about the assignment of the study groups. Pharmaceuticals are provided by a third party who is a pharmacy staff, and the researcher himself is informed of the medicinal contents according to the code on the package.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Arak university of medical sciences, Arak

City
Arak

Province
Markazi

Postal code
۳۸۱۹۶۹۳۴۵۰

Approval date
2023-09-26, 1402/07/04

Ethics committee reference number
IR.ARAKMU.REC.1402.153

Health conditions studied

1

Description of health condition studied
Ulcerative proctitis

ICD-10 code
K51.2

ICD-10 code description
Ulcerative (chronic) proctitis

Primary outcomes

1

Description
Severity of disease activity

Timepoint
Start of study and 3 and 6 months later

Method of measurement
Simple Clinical Colitis Activity Index (SCCAI) And Disease Activity Index (DAI)

2

Description
Response to treatment

Timepoint
Start of study and 6 months later

Method of measurement
Colonoscopy and Biopsy

3

Description
Laboratory criteria

Timepoint
Start of study and 3 and 6 months later

Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients treated with Mesalazine suppositories at the rate of one gram per day for 6 months.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients treated with oral Mesalazine at the rate of 3 grams per day along with Mesalazine suppositories of 1 gram per day for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Esmaeil Mirshafie
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Doctor Davood Hekmat Pou
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Esmaeil Mirshafiee
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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