

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Clinical efficacy of Mesalazine in patients with diarrhea-dominant irritable bowel syndrome with elevated fecal calprotectin referred to Emam Reza Hospital of Tabriz: a randomized double-blind, placebo-controlled trial

Protocol summary

Study aim

The effect of mesalazine on clinical symptoms and fecal calprotectin levels in patients with irritable bowel syndrome with a predominance of diarrhea and high calprotectin

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients. For randomization, blockrandomization method is used in two groups of control (n = 45) and drug (n = 45).

Settings and conduct

The present study is a double-blind randomized clinical trial (researcher and patient) that will be performed on patients with irritable bowel syndrome referred to gastrointestinal clinics affiliated to Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with irritable bowel syndrome;; diagnosed with Rome IV according to the opinion of a physician; predominant symptoms of patients are diarrhea; normal stool calprotectin level; normal colonoscopy.

Intervention groups

The study groups will receive 500 mg of mesalazine tablets 2 times a day for 8 weeks or placebo for 8 weeks.

Main outcome variables

Abdominal pain; bloating; Diarrhea; use of mesalazine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151106024901N5**

Registration date: **2021-08-24, 1400/06/02**

Registration timing: **retrospective**

Last update: **2021-08-24, 1400/06/02**

Update count: **0**

Registration date

2021-08-24, 1400/06/02

Registrant information

Name

Seyyed Mehdi Rasoolimanesh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

m_rasulimanesh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical efficacy of Mesalazine in patients with diarrhea-dominant irritable bowel syndrome with elevated fecal calprotectin referred to Emam Reza Hospital of Tabriz: a randomized double-blind, placebo-controlled trial

Public title

Clinical efficacy of Mesalazine in patients with diarrhea-

dominant irritable bowel syndrome with elevated fecal calprotectin referred to Emam Reza Hospital of Tabriz: a randomized double-blind, placebo-controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with IBS-D according to ROME IV criteria (Loose and watery stool at at least 25% and hardy stool less than 25% of bowel movement) Age over 18 years Predominant symptom of diarrhea Calprotectin levels above 50 feces Normal colonoscopy during the last 5 years

Exclusion criteria:

Pregnancy and lactation and those who plan to become pregnant History of major abdominal surgery other than appendectomy and cholecystectomy A history of allergic disease such as asthma in yourself or a first-degree relative Celiac disease History of known psychological disease Consumption of anti-inflammatory drugs (corticosteroids, NSAIDs), mast cell stabilizers and antibiotics in the last 3 months History of inflammatory bowel disease or ulcerative colitis Sensitivity to sulfur-containing compounds such as mesalazine Consumption of lactulose and recent probiotics Evidence of organic disease in colonoscopy Normal stool calprotectin

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple. Randomization unit: individual. Randomization tool: sealed envelope The researcher assigned individuals into two groups using lottery (selecting sealed envelopes, with a card with the letters M or C inside them).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient and the researcher are kept blind. In this way, the safety and data monitoring committee know whether it is a placebo or a drug, and the researcher and the patient do not know the type of group. In this regard, the drug and the placebo will be packed in the same boxes. The drug and placebo will be packaged and delivered by the committee in separate envelopes, and the researcher will divide the patients into two groups, by giving envelope A or envelope B.

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

Imam Reza Hospital, Golgasht St., Daneshgah St., Tabriz, East Azerbaijan Province

City

tabriz

Province

East Azarbaijan

Postal code

51666 14756

Approval date

2020-11-09, 1399/08/19

Ethics committee reference number

IR.TBZMED.REC.1399.786

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

abdominal pain

Timepoint

Before and 8 weeks after the intervention

Method of measurement

visual analog scale (0=no pain; 10= worst pain)

2

Description

bloating

Timepoint

Before and 8 weeks after the intervention

Method of measurement

Based on a questionnaire

3

Description

Diarrhea

Timepoint

Before and 8 weeks after the intervention

Method of measurement

Based on the prepared questionnaire, the number of diarrhea per day will be measured.

4

Description

Consumption of mesalazine

Timepoint

Before and 8 weeks after the intervention

Method of measurement

Based on a questionnaire

5

Description

Fecal calprotectin levels

Timepoint

Before and 8 weeks after the intervention

Method of measurement

ELISA method with laboratory kit (calprest)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 mg mesalazine tablets 2 times a day for 8 weeks and patients 'clinical manifestations will be evaluated by a physician.

Category

Treatment - Drugs

2

Description

Control group: received placebo 2 times a day for 8 weeks and patients 'clinical manifestations will be evaluated by a physician.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Tabriz University of Medical Sciences Imam Reza hospital

Full name of responsible person

Seyed Mehdi Rasoulimanesh

Street address

Imam Reza hospital, Golgasht Street, University Street

City

Tabriz

Province

East Azarbaijan

Postal code

51666 14756

Phone

+98 41 3337 3993

Email

m_rasulimanesh@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Golgasht Street, University Street

City

Tabriz

Province

East Azarbaijan

Postal code

51666 14756

Phone

+98 41 3335 7310

Email

samiei.moh@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

Seyyed Mehdi Rasoolimanesh

Position

Subspecialized assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Golgasht Street,University Street

City

Tabriz

Province

East Azarbaijan

Postal code

51666 14756

Phone

+98 31 5554 0021

Fax

+98 31 5554 0021

Email

m_rasulimanesh@kaums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Rasoolimanesh

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Internal Medicine

Street address

Golgasht Street,University Street

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Tabriz

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Postal code

51666 14756

Phone

+98 31 5554 0021

Fax

+98 31 5554 0021

Email

m_rasulimanesh@kaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Rasoolimanesh

Position

Subspecialized assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Golgasht Street,University Street

City

Tabriz

Province

East Azarbaijan

Postal code

51666 14756

Phone

+98 31 5554 0021

Fax

+98 31 5554 0021

Email

m_rasulimanesh@kaums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

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