

# 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

**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 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