

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Mesalamine effects on mucosal immune biomarkers in irritable bowel syndrome with diarrhea-predominant symptoms

Protocol summary

Summary

Main goals: The effect of Mesalamine on immune biomarker in IBS in comparison with placebo. Inclusion criteria: 1-Consent to participate in the study and signing the consent form; 2- being at the age of 18 years and older. Exclusion criteria: 1 - Pregnancy or breast feeding; 2 - not using appropriate contraceptive methods; 4 - Use of corticosteroids, antibiotics, mast cell stabilizing drugs, NSAIDs; 5- Large abdominal surgery; 6 - Celiac disease (positive Anti TTG and Anti EndomysialAb); 7 - specific allergic diseases like asthma (positive family and personal history and positive Anti IGE). Sample size: 29 patients in the intervention group and 29 in the comparison group. Type of study: Double blind randomized Clinical trial. Definition of outcome: we have achieved the goal of therapy in case of significant difference in the number of mucosal mast cells and presence of inflammatory mediators in biopsy of the left colon which is taken before and after the treatment, resolving complaints of IBS patients such as changes in bloating, abdominal pain, urgency of defecation, number of daily bowel movements, stool form and consistency, easy defecation, feeling empty and well being. Patients who are satisfied in at least 50% of the weeks of treatment have responded to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072910230N2**

Registration date: **2012-12-17, 1391/09/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-17, 1391/09/27

Registrant information

Name

Homayoon Vahedi

Name of organization / entity

Digestive Disease Research Center ,Tehran University
Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8241 5104

Email address

vahedi@ams.ac.ir

Recruitment status

Recruitment complete

Funding source

Digestive and Liver Disease Research Center, Shariati
Hospital

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2013-06-20, 1392/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Mesalamine effects on mucosal immune biomarkers in
irritable bowel syndrome with diarrhea-predominant
symptoms

Public title

Mesalamine effects on mucosal immune biomarkers in
irritable bowel syndrome with diarrhea-predominant
symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Consent to participate in the study and signing the consent form; 2 - being at the age of 18 years and older. Exclusion criteria: 1 - Pregnancy or breast feeding; 2 - not using appropriate contraceptive methods; 3 - the use of NSAIDs; 4 - Use of corticosteroids, antibiotics, mast cell stabilizing drugs; 5- Large abdominal surgery; 6 - Celiac disease (positive Anti TTG and Anti Endomysial Ab); 7 - specific allergic diseases like asthma (positive family and personal history and positive Anti IGE); 8 - organic or psychological disorders characterized by history and specific laboratory tests; 9 - lack of cooperation in implementation of the Study.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

the sixth floor of the Central University, Ghods st.,
Keshavarz Blvd

City

Tehran

Postal code

1417613151

Approval date

2012-10-20, 1391/07/29

Ethics committee reference number

91/210/14833/5

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

K58.0

ICD-10 code description

Irritable bowel syndrome with diarrhoea

Primary outcomes

1

Description

Mucosal biomarkers

Timepoint

Before the study and at the end of study

Method of measurement

Sample Pathology

2

Description

Symptoms (diarrhea - abdominal pain - bloating - urgency - the number of bowel movements per day)

Timepoint

Baseline, during and at the end of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Number of mast cell

Timepoint

Beginning and end of the intervention

Method of measurement

Sample pathology

2

Description

IHC CD117

Timepoint

Beginning and end of the intervention

Method of measurement

Sample pathology

3

Description

Gastrointestinal side effects (diarrhea - bloating - constipation)

Timepoint

Initially, during and end of treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Mesalamine 800 mg three times a day for 2 months

Category

Treatment - Drugs

2

Description

placebo 3 times daily

Category

Treatment - Drugs

3

Description

Colonoscopy and biopsy at baseline and end of treatment

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr. Mehri Pouradineh

Street address

North Kargar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Digestive and Liver Disease Research Center, Shariati Hospital

Full name of responsible person

Doctor shahin merat

Street address

Shariati Hospital, North Kargar Street, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Digestive and Liver Disease Research Center, Shariati Hospital

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Rossen Darman company

Full name of responsible person

Dr. Heydri

Street address

Head Office, Fourth Floor of No. 33, cross Sarparast and Bozorgmehr

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rossen Darman company

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Research Center for Gastroenterology and Liver

Full name of responsible person

Dr. Homayon Vahedi

Position

Associate Professor

Other areas of specialty/work

Street address

Gastrointestinal and Hepatic Research Center, Shariati Hospital, North Kargar Avenue

City

Tehran

Postal code

Phone

+98 21 84901

Fax

Email

vahedi@ams.ac.ir

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Digestive and Liver Disease Research Center, Shariati Hospital

Full name of responsible person

Dr. Homayon Vahedi

Position

Associate Professor

Other areas of specialty/work

Street address

Gastrointestinal and Hepatic Research Center, Shariati Hospital, North Kargar Avenue

City

Tehran

Postal code

Phone

+98 21 84901

Fax

Email

vahedi@ams.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Digestive and Liver Disease Research Center, Shariati Hospital

Full name of responsible person

Dr. mehri pouradineh

Position

internal Assistant

Other areas of specialty/work

Street address

Gastroenterology Research Center, Shariati Hospital

City

Tehran

Postal code

Phone

+98 21 84901

Fax

Email

mehri_pooradineh@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty