

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Clinical efficacy and safety of loratadine in treating irritable bowel syndrome with predominant diarrhea

Protocol summary

Study aim

Evaluation the clinical efficacy of Loratadine on GI symptoms of IBS-D patients

Design

A Phase3, randomized, blinded pilot clinical trial with parallel groups design of 32 patients. random allocation process is done by permuted block randomization.

Settings and conduct

The patients with IBS-D referred to the Omid GI Clinic of Ayatollah Rouhani Hospital are randomly divided into a Loratadine group and a control group. The patients in the Loratadine group receive Loratadine tablets(10mg, oral) once daily and Patients in the control group receive oral Placebo once daily for 4-6 weeks. The patients are followed up once in every 2weeks for 6-8weeks and Gastrointestinal symptoms will be assessed before and after treatment. biographic information, symptoms, response to treatment and adverse drug reactions will be recorded in data collection forms designed for each patient and analyzed. In this study participants, the main researcher, clinicians ,the data collector, and the Data safety and Monitoring Committee are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with IBS-D: Age between 18 and 65! No abnormalities observed by Sigmoidoscopy!
Exclusion criteria: Diabetes! Renal impairment!
Cardiovascular disorders! Colitis! Celiac disease! Use of drugs that affect the digestive system

Intervention groups

The patients in the Loratadine group receive Loratadine tablets(10mg, oral) once daily for 4-6 weeks. (if patients do not response to the treatment the dose will be increased to 10mg twice daily).Patients in the control group receive oral Placebo once daily for 4-6 weeks. also all patients receive routine therapeutic regimen of IBS-D (Amitriptyline 10mg, Loperamide and diphenoxylate).

Main outcome variables

Diarrhea frequency! Pain severity! Abdominal pain frequency! defecation urgency! bloating.

General information

Reason for update

Our study aimed to investigate the efficacy and safety of loratadine in a clinical trial study with 100 patients. According to the coronavirus pandemic, our sampling got into trouble, Our hospital was the COVID-19 patient admission center, on the other hand, most patients didn't get serious their IBS-D disease during the COVID-19 pandemic, so referrals to our GI clinic reduced significantly. Finally, the number of participants had the study inclusion criteria reduced to 40 patients in a year and a half, According to this situation, we request to register our study as a randomized pilot clinical trial Because of our time limitation, if appropriate.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201221049782N1**
Registration date: **2021-04-16, 1400/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-26, 1401/04/05**

Update count: **1**

Registration date

2021-04-16, 1400/01/27

Registrant information

Name

Faezeh Vahidi Motlagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3221 0660

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faezehvdi1997@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

2021-02-28, 1399/12/10

Actual recruitment end date

2022-03-19, 1400/12/28

Trial completion date

2022-05-12, 1401/02/22

Scientific title

Clinical efficacy and safety of loratadine in treating irritable bowel syndrome with predominant diarrhea

Public title

Loratadine in treating irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with IBS-D Age between 18 and 65 No abnormalities on physical examination Routine CBC No abnormalities observed by Sigmoidoscopy Normal thyroid function Negative routine stool examinations

Exclusion criteria:

Diabetes Renal impairment Cardiovascular disorders Psychiatric disorders Colitis Celiac disease Use of drugs that affect the digestive system Use of Analgesics Use of Antihistamines Loratadine intolerance

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with IBS-D are randomly divided into a Loratadine group and a control group. random allocation process is done by permuted block randomization. 25 Blocks (with 4 subjects per block and AABB permutations) is made by Randomization.com Website and placed on the same drug packages by coding. Letters A and B, the intended permutation and other required information are entered in randomization website. 100 phrases with letters A or B are achieved, which randomly indicate Who should take loratadine and who should take placebo from the first to the hundredth patient, (A=loratadine ,B=placebo).

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a randomized controlled trial (RCT), In this study, participants, the main researcher, clinicians, the data collector, and the Data Safety and Monitoring Committee are blinded. Participants are asked by the blinded clinician to eat the drug . All of the drugs are packaged the same, but some are the Loratadine tablets while others are Placebos. The blinded data collector collects data from patients every 2weeks. In the end, the Data collected from both groups are analyzed by data analysts.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of babol university of medical sciences

Street address

Babol university of medical sciences, Ganjafrooz street, babol

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۱۳۶۷

Approval date

2021-01-30, 1399/11/11

Ethics committee reference number

IR.MUBABOL.REC.1399.463

Health conditions studied**1****Description of health condition studied**

Irritable bowel syndrome with diarrhea

ICD-10 code

K58.0

ICD-10 code description

Irritable bowel syndrome with diarrhea

Primary outcomes**1****Description**

Diarrhea Frequency

Timepoint

before treatment and 14, 28, 42 and 56 days after beginning of treatment

Method of measurement
questionnaire

2

Description

Severity of pain

Timepoint

before treatment and 14, 28, 42 and 56 days after beginning of treatment

Method of measurement
questionnaire

3

Description

Abdominal pain frequency

Timepoint

before treatment and 14, 28, 42 and 56 days after beginning of treatment

Method of measurement
questionnaire

4

Description

defecation urgency

Timepoint

before treatment and 14, 28, 42 and 56 days after beginning of treatment

Method of measurement
questionnaire

5

Description

bloating

Timepoint

before treatment and 14, 28, 42 and 56 days after beginning of treatment

Method of measurement
questionnaire

Secondary outcomes

1

Description

Quality of life score

Timepoint

before treatment and 14, 28, 42 and 56 days after beginning of treatment

Method of measurement
Irritable bowel syndrome-Quality of life questionnaire(IBS-QOL)

Intervention groups

1

Description

Intervention group: The patients in the Loratadine group receive Loratadine tablets(10mg, oral) made by Pharmachemie pharmaceutical company once daily for 4-6 weeks (if patients do not response to the treatment the dose will be increased to 10mg twice daily), also they receive routine therapeutic regimen of IBS-D (Amitriptyline 10mg, Loperamide and diphenoxylate).

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group receive oral Placebo made by Pharmachemie pharmaceutical company once daily for 4-6 weeks. also they receive routine therapeutic regimen of IBS-D (Amitriptyline 10mg, Loperamide and diphenoxylate).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Specialty and subspecialty clinic of Ayatollah rouhani hospital

Full name of responsible person

Hasan Abedi Valoukolaie

Street address

Omid Specialty and subspecialty clinic, Ayatollah rouhani hospital, Ganjafrouz street

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4717641367

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Email

rohani@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmachemie pharmaceutical factory

Full name of responsible person

Motahare rouhi

Street address

No. 2, West forth Ave., sixteenth Street, before Azadegan, 8kilometers of Karaj_Tehran road, Tehran, Iran

City

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1389794581
Phone
+98 21 4452 5190
Email
info@pharmachemie.co
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Pharmachemie pharmaceutical factory
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Fatere seyedalipour
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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