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

Email address

faezehvhdi1997@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

City

Babol

Province

Mazandaran

Postal code

4717641367

Phone

+98 11 3220 0487

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

Tehran
Province
Tehran
Postal code
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
Babol University of Medical Sciences
Full name of responsible person
Fatere seyedalipour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Medicinal Care unit, first floor, Babol university of medical science, Ganjafrooz street, babol
City
Babol
Province
Mazandaran
Postal code
4717641367
Phone
+98 11 3223 8301
Email
f_seyedalipour@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Fatere seyedalipour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Medicinal Care unit, first floor, Babol university of medical science, Ganjafrooz street, babol
City
Babol
Province
Mazandaran
Postal code
4717641367
Phone
+98 11 3223 8301
Email
f_seyedalipour@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Faezeh Vahidi Motlagh
Position
Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
No. 41, Sepidar1, Spidar Ave., Shohadaye gomnam Square
City
bojnord
Province
North Khorasan
Postal code
9416741196
Phone
+98 58 3221 0660
Email
faezehvhdi1997@gmail.com

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