Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effectiveness of rifaximin at doses of 1650mg and 2200mg in the treatment of patients with diarrhea-predominant irritable bowel syndrome.

Protocol summary

Study aim
Comparison of effectiveness of rifaximin at doses of 1650mg and 2200mg in the treatment of patients with diarrhea-predominant irritable bowel syndrome.

Design
This is an open-label, parallel, phase III and randomized clinical trial with control group. Randomization is done using SPSS software. The estimated sample size is 150 patients.

Settings and conduct
Place of study: clinic of digestive diseases at Rasoul-e-Akram Hospital, Tehran, Iran; The target population: adult patients with diarrhea-predominant irritable bowel syndrome; Blinding: there is no blinding in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Diarrhea-dominant IBS patients ; who are available for the entire study period; 16-70 years old. Exclusion criteria: other sub-classes of IBS; Antibiotic and probiotics therapy in the last 3 months; inflammatory bowel disease.

Intervention groups
Control group: 550mg capsule of Rifaximin three times a day. Intervention group: 550mg capsule of Rifaximin four times a day.

Main outcome variables
abdominal pain, stool consistency, frequency/urgency in defecation, and the quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141201020178N12**
Registration date: **2023-08-31, 1402/06/09**
Registration timing: **registered_while_recruiting**
Last update: **2023-08-31, 1402/06/09**
Update count: **0**

Registration date
2023-08-31, 1402/06/09

Registrant information

Name
Marjan Mokhtare

Name of organization / entity
Iran University of Medical sciences,Rasoul Akram Hospital,Colorectal Research Center

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-10-06, 1402/07/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of effectiveness of rifaximin at doses of 1650mg and 2200mg in the treatment of patients with diarrhea-predominant irritable bowel syndrome.

Public title
The therapeutic effects of rifaximin in diarrhea-

predominant irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diarrhea-dominant irritable bowel syndrome (IBS-D) patients based on ROME IV criteria Patients who are available for the entire study period Women and men among Iranian population with more than 16 years old Patients who are able to follow the study protocol

Exclusion criteria:

Mild IBS-D (less than 175 points on the IBS-SSS scale) All IBD subtypes Consumption of Antibiotics or probiotics in the past three months before trial A severe concomitant disease (malignancy, hypertension uncontrolled and diabetes mellitus, liver, kidney or heart disorders, serious neurological disorders, psychosis, respiratory disorders such as asthma, chronic obstructive pulmonary disease, hyperthyroidism or hypothyroidism) Diagnosed lactose intolerance Consumption of motility medications or dietary fiber supplements 2 weeks before the start of the study Planning to undergo surgery during the study period History of alcohol or drug abuse Chronic bowel disorders other than IBS, including inflammatory bowel disease, gastric and duodenal ulcers, celiac disease Participation in another clinical trial within the past three months Positive PCR result for the COVID-19 Pregnancy or breastfeeding

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Computer-generated, simple randomization with SPSS software into two equally numbered groups. After recruiting the eligible subjects and dedicating distinctive IDs to each patient, patients will be randomly allocated into two equal groups using the randomization command in SPSS software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, West Shahid Hemmat Highway, Intersection of Chamran and Sheikh Fazlollah Noori

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-06-11, 1402/03/21

Ethics committee reference number

IR.IUMS.FMD.REC.1402.135

Health conditions studied

1

Description of health condition studied

diarrhea-predominant irritable bowel syndrome

ICD-10 code

K58.0

ICD-10 code description

Irritable bowel syndrome with diarrhea

Primary outcomes

1

Description

Abdominal pain

Timepoint

Before the treatment, at the end of treatment, 4 and 8 weeks after completing treatment

Method of measurement

IBS-D symptom severity index questionnaire

2

Description

Bloating

Timepoint

Before the treatment, at the end of treatment, 4 and 8 weeks after completing treatment

Method of measurement

IBS-D symptom severity index questionnaire

3

Description

Defecation frequency/urgency

Timepoint

Before the treatment, at the end of treatment, 4 and 8

weeks after completing treatment

Method of measurement

IBS-D symptom severity index questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and after the treatment course

Method of measurement

IBS-D quality of life questionnaire.

2

Description

Stool consistency

Timepoint

Before the treatment, at the end of treatment, 4 and 8 weeks after completing treatment

Method of measurement

bristol stool form scale

3

Description

Safety

Timepoint

At the end of treatment, 4 and 8 weeks after completing treatment

Method of measurement

recorded by physicians and patients using data gathering sheets

4

Description

Tolerability

Timepoint

At the end of treatment, 4 and 8 weeks after completing treatment

Method of measurement

Recorded by physicians and patients using data gathering sheets

Intervention groups

1

Description

Control group: 550mg capsule of rifaximin three times a day for 10 days

Category

Treatment - Drugs

2

Description

Intervention group: 550mg capsule of rifaximin four times a day for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology department, Rasoul Akram Hospital

Full name of responsible person

Marjan Mokhtare

Street address

Rasoul Akram Hospital; Sattarkhan Street; Niayesh Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hosein Keyvani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Marjan Mokhtare

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Adult Gastroenterology and Hepatology

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

N/A

When the data will become available and for how long

N/A

To whom data/document is available

N/A

Under which criteria data/document could be used

N/A

From where data/document is obtainable

N/A

What processes are involved for a request to access data/document

N/A

Comments