

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6652 2845

###### Email address

mokhtare.m@iums.ac.ir

##### 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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**Email**

marjanmokhtare@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hosein Keyvani

**Street address**

Iran University of Medical Sciences; Hemmat Blvd

**City**

Tehran

**Province**

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keyvani.h@iums.ac.ir

**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**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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