Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A comparison between the effect of rifaximin in different doses on symptoms and quality of life improvement in Iranian patients with diarrhea-predominant irritable bowel syndrome, a randomized clinical trial.

Protocol summary

Study aim

A comparison between the effect of rifaximin in different doses on symptoms and quality of life improvement in Iranian patients with diarrhea-predominant irritable bowel syndrome, a randomized clinical trial.

Design

All eligible patients are informed about the study design and after completing the consent form, based on the randomized table, assigned in one of the treatment groups. The total number of patients is 160 patients, with 80 patients in each group.Demographic data were recorded. Questionnaires including IBS-D SSI, QOL and Beck score and Bristole score are recoreded at the beginning and ending the treatment and 4 and 8 weeks after ending the treatments.

Settings and conduct

All eligible patients with diarrhea dominant IBS who are referred to the gastroenterology clinic of Rasoul Akram hospital, after filling informed-consent form, will be randomly assigned into two treatment groups. IBS-D SS Index, IBS-D QoL, Bristol stool scale, Beck anxiety and depression will be completed for all the patients at the beginning, end of treatment, and 4 and 8 weeks after completing the treatment. Data is analyzed by SPPS version 21.

Participants/Inclusion and exclusion criteria

All patients with diarrhea dominant irritable bowel syndrome based on Rome IV criteria with the age 16-70 years

Intervention groups

Control group: 550mg capsule of rifaminin twice a day intervention group : 550mg capsule of rifaminin three times a day

Main outcome variables

Improvement of IBS-D patients' symptoms severity index improvement of IBS-D patients' quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141201020178N11**
Registration date: **2022-04-03, 1401/01/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-03, 1401/01/14**
Update count: **0**

Registration date

2022-04-03, 1401/01/14

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)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-04-08, 1401/01/19

Actual recruitment start date

2022-01-20, 1400/10/30

Actual recruitment end date

2022-04-08, 1401/01/19

Trial completion date

2022-09-20, 1401/06/29

Scientific title

A comparison between the effect of rifaximin in different doses on symptoms and quality of life improvement in Iranian patients with diarrhea-predominant irritable bowel syndrome, a randomized clinical trial.

Public title

The effect of rifaximin in different doses on symptoms and quality of life improvement in Iranian patients with diarrhea-predominant irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diarrhea-dominant IBS (IBS-D) patients Patients who are able to follow the study protocol Patients who are available for the entire study period Women and men amongst Iranian population 16-70 years old patients

Exclusion criteria:

All patients with other subclass of IBS Probiotics consumption in the last 3 months Antibiotic therapy in the last 3 months Concomitant systemic disease (malignancy, uncontrolled hypertension, diabetes mellitus, liver, kidney, pulmonary or heart diseases, neurological disorders, psychosis, thyroid dysfunction, lactose intolerance, pregnancy or breastfeeding, inflammatory bowel disease, celiac disease, and gastroduodenal disease) Taking fiber supplements within 2 weeks before starting the study Planning to have surgery during the study time History of alcohol or drug abuse Participating in another clinical trial over the past three months Positive PCR result for covid 19

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: **200**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

computer-generated ,simple randomization with interactive web response system(IRS) into two equally-numbered groups

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 science

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

2021-06-19, 1400/03/29

Ethics committee reference number

IR.IUMS.FMD.REC.1400.213

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

Comparison of improvement in IBS-D patients symptom severity index between treatment groups.

Timepoint

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

Method of measurement

IBS-D symptom severity index questionnaire

2

Description

Comparison of improvement in IBS-D patients quality of life between treatment groups.

Timepoint

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

Method of measurement

IBS-D quality of life questionnaire.

Secondary outcomes

1

Description
comparison of improvement in quality of life
Timepoint
At the beginning, at the end of treatment, 4 and 8 weeks after end of the treatment.
Method of measurement
Bristol stool texture score

2

Description
comparison of improvement in IBS-D anxiety and depression score
Timepoint
At the beginning and end of the treatment
Method of measurement
Beck depression and anxiety score

Intervention groups

1

Description
Control group: 550mg capsule of rifaximin twice a day
Category
Treatment - Drugs

2

Description
Intervention group: 550mg capsule of rifaximin three times in a day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology department, Rasoul Akram Hospital
Full name of responsible person
Marjan Mokhtare
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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