

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of rifaximin tablets on the quality of life and symptoms of irritable bowel syndrome in patients

Protocol summary

Study aim

Investigating the effect of rifaximin tablets on quality of life and symptoms of irritable bowel syndrome

Design

Randomization in this study will be done using block randomization method with online software in 29 blocks of 6.

Settings and conduct

This study will be conducted as a randomized clinical trial in Amir al-Momenin Hospital in Arak, on patients with irritable bowel syndrome. In this study, the quality of life questionnaire is filled before starting the treatment, and after taking the medicine for two weeks, the questionnaire is filled and the recovery rate of the patients is checked. This study will be conducted in a double-blind manner, and patients and clinical caregivers and outcome assessors will not know the type of study groups.

Participants/Inclusion and exclusion criteria

Normal body mass index (18-25) Absence of any organic intestinal disease and intestinal infection Absence of any major intestinal surgery Not taking laxatives or antidiarrheal drugs regularly Lack of medical history of gastrointestinal and colorectal diseases and absorption Lack of regular use of antibiotics and corticosteroids and immunosuppressive drugs Not taking drugs that increase bleeding from intestinal mucus such as aspirin, warfarin Absence of severe mental and behavioral disorder Not being pregnant or breastfeeding, being an athlete or being hospitalized Not taking non-steroidal anti-inflammatory drugs Absence of breast cancer in the person himself or first degree relatives

Intervention groups

In this research, 30 patients with irritable bowel syndrome are selected and receive rifaximin drug for two weeks, and the control group, 30 patients received placebo drug for two weeks, and after that, all patients using The quality of life questionnaire of irritable bowel syndrome patients will be examined.

Main outcome variables

Quality of life, Clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221211056775N1**

Registration date: **2022-12-18, 1401/09/27**

Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**

Update count: **0**

Registration date

2022-12-18, 1401/09/27

Registrant information

Name

Yasin Aziminezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3367 3552

Email address

yassazzim74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-10, 1401/10/20

Expected recruitment end date

2023-02-09, 1401/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of rifaximin tablets on the quality of life and symptoms of irritable bowel syndrome in patients

Public title

The effect of rifaximin in IBS

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Normal body mass index (18-25) Absence of any organic intestinal disease (diagnosis based on colonoscopy in the last 5 years) and absence of any intestinal infection (diagnosis based on stool culture) Absence of any major intestinal surgery Not taking laxatives or antidiarrheal drugs regularly Lack of medical history of gastrointestinal and colorectal diseases and absorption Lack of regular use of antibiotics and corticosteroids and immunosuppressive drugs Not taking drugs that increase bleeding from intestinal mucus such as aspirin, warfarin Absence of severe mental and behavioral disorder Not being pregnant or breastfeeding, being an athlete or being hospitalized Not taking non-steroidal anti-inflammatory drugs Absence of breast cancer in the person herself or first degree relatives

Exclusion criteria:

Taking rifaximin tablets from one year before entering the study and changing the diet during the study Failure to continue the study due to drug side effects Reluctance to cooperate Pregnancy during study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

This study will be conducted in a double-blind manner. In this way, participating patients and clinical caregivers and outcome assessors are not aware of the study groups and know them only based on the letters A and B. Of course, the main researcher and data analyst are aware of the studied groups and the interventions performed in them.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Student Research Committee , Arak University of Medical Sciences , Arak ,Iran

Street address

Arak, University Street, Modares Street, Yas dead end

City

Arak

Province

Markazi

Postal code

3817915193

Approval date

2022-10-23, 1401/08/01

Ethics committee reference number

IR.ARAKMU.REC.1401.212

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

Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

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

Quality of life

Timepoint

Two weeks before and two weeks after the intervention

Method of measurement

Specific quality of life questionnaire for patients with irritable bowel syndrome (IBS_QOL)

2**Description**

Clinical symptoms

Timepoint

Two weeks before and two weeks after the intervention

Method of measurement

Clinical interview

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients fill out the questionnaire related to the quality of life of irritable bowel syndrome 2 weeks before starting to take rifaximin tablets and record the symptoms they had before starting the drug. Since the beginning of the study, rifaximin 550 mg tablets (Kowsar-Iran) have been taken orally every 12 hours, once a day. Then, 2 weeks after taking the drug, they fill out the quality of life questionnaire again.

Category

Treatment - Drugs

2

Description

Control group: 30 patients fill out the irritable bowel syndrome quality of life questionnaire 2 weeks before starting the placebo pill and record the symptoms they had before starting the drug. Since the beginning of the study, placebo pills, similar to the medicine of the intervention group, have been taken orally every 12 hours, one tablet per day. Then, 2 weeks after taking the drug, they fill out the quality of life questionnaire again.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-momenin Hospital

Full name of responsible person

Hamidrea Norozi

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University Street, Modares St., dead end, Yas

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammadreza Rohani

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Yasin Aziminezhad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Yasin Aziminezhad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available