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

Street address
University Street, Modares St., dead end, Yas

City
Arak

Province
Markazi

Postal code
3817915193

Phone
+98 86 3367 3552

Email
yassazzim74@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohammadreza Rohani

Street address
University Street, Modares St., dead end, Yas

City
Arak

Province
Markazi

Postal code
3817915193

Phone
+98 86 3367 3552

Email
yassazzim74@gmail.com

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

Street address
University Street, Modares Street,Yas 4 dead end

City
Arak

Province
Markazi

Postal code
3817915193

Phone
+98 86 3367 3552

Email
yassazzim74@gmail.com

Person responsible for scientific 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
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Email
yassazzim74@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

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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