Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the Efficacy of Escitalopram, Venlafaxine and Buspirone on the Symptoms and Quality of Life in Irritable Bowel Syndrome Patients

Protocol summary

Study aim
Comparison of the Efficacy of Escitalopram, Venlafaxine and Buspirone on the Symptoms and Quality of Life in Irritable Bowel Syndrome Patients

Design
Clinical trial with parallel groups, single blind and randomized on 90 patients

Settings and conduct
Three groups of 30 patients with irritable bowel syndrome will be treated with one of the three escitalopram, venlafaxin or buspirone drugs for 8 weeks in three parallel groups. Medications are given in capsule form and patients do not know what type of drug they are taking.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Diagnosis of irritable bowel syndrome; Patient's written consent to participate in the study Exclusion Criteria: Age less than 18 years; Allergies to citalopram, venlafaxin or buspirone; The presence of warning signs such as chronic fever, weight loss, gastrointestinal bleeding; pregnancy and lactation; The use of any medication that can affect the bowel function (such as laxatives, antidiarrhea, antibiotics and probiotics) within one month before entering the study; Known cases of lactose intolerance; Severe physical illnesses, mental retardation, dementia, psychosis, and the existence of serious suicidal ideation and substance dependence that affects patients' compliance with the study protocol

Intervention groups
Intervention group 1: Daily 10-20 milligram of Escitalopram manufactured in Sobhan Pharmaceutical Company for eight weeks Intervention group 2: 75-375 milligram of Venlafaxine manufactured in Abidi Pharmaceutical Company for eight weeks Intervention group 3: Daily 15-60 milligram of Buspirone manufactured in Sobhan Pharmaceutical Company for eight weeks

Main outcome variables
Irritable bowel syndrome symptoms; Patient's quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150630022991N10**
Registration date: **2018-03-21, 1397/01/01**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-21, 1397/01/01**
Update count: **0**

Registration date
2018-03-21, 1397/01/01

Registrant information

Name
Sussan Moudi

Name of organization / entity
Babol University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 11 3236 5683

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sussan.mouodi@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-07-22, 1397/04/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Escitalopram, Venlafaxine and Buspirone on the Symptoms and Quality of Life in Irritable Bowel Syndrome Patients

Public title

Efficacy of Escitalopram, Venlafaxine and Buspirone in Irritable Bowel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The Presence of ROME-III Diagnostic Criteria for Diagnosis of Irritable Bowel Syndrome To Provide the Informed Consent Form of the Patient for Participation in the Study

Exclusion criteria:

Age under 18 years Allergy to Escitalopram, Venlafaxine or Buspirone The presence of warning signs such as chronic fever, weight loss, gastrointestinal bleeding Pregnancy and breast feeding Use of any drug that can affect the bowel function (such as laxatives, anti-diarrhea, antibiotics and probiotics) within one month before entering the study Known cases of lactose intolerance Severe physical illnesses, mental retardation, dementia, psychosis, and the existence of serious suicidal ideation and substance dependence that affects patients' compliance with the study protocol

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The individuals are randomly assigned to one of the three study groups with the help of a random number table and receive the intervention of the same group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In each of the three study groups, the drug is delivered to the patient in the form of a capsule, and the patient does not know what type of drug is used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Ganjafrooz Avenue, Babol

City

Babol

Province

Mazandaran

Postal code

4136747176

Approval date

2017-10-15, 1396/07/23

Ethics committee reference number

MUBABOL.REC.1396.70

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

Irritable bowel syndrome symptoms

Timepoint

Baseline assessment and at the end of the eighth week of intervention

Method of measurement

According to ROME-III diagnostic criteria

2

Description

Patient´s quality of life

Timepoint

Baseline assessment and at the end of the eighth week of intervention

Method of measurement

According to the quality of life questionnaire IBS_QOL

Secondary outcomes

1

Description
The drug side effects
Timepoint
At the fourth and eighth weeks of the intervention
Method of measurement
Visit of the patient

Intervention groups

1

Description
Intervention group 1: Daily 10-20 milligram Escitalopram manufactured in Sobhan Pharmaceutical Company for 8 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2: Daily 75-375 milligram Venlafaxine manufactured in Abidi Pharmaceutical Company for 8 weeks
Category
Treatment - Drugs

3

Description
Control group: Daily 15-60 milligram Buspirone manufactured in Sobhan Pharmaceutical Company for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Sussan Moudi, MD
Street address
Ayatollah Rouhani Hospital, Ganjafrooz avenue, Babol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi, MD, PhD
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rezaghadimi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Sussan Moudi, MD
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Web page address

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is 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
Information related to the main outcomes of the study will be available for sharing.

When the data will become available and for how long
After publishing the final manuscript

To whom data/document is available
Researchers working in the universities

Under which criteria data/document could be used
After the final manuscript is published, the data will be available to academic researchers upon request.

From where data/document is obtainable
Sussan Moudi, MD, email: sussan.mouodi@gmail.com

What processes are involved for a request to access data/document
Upon receipt of a written request from the applicant, the requested documentation will be e-mailed within a maximum of one month.

Comments