Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of duloxetine in quality of life and symptoms of patients with irritable bowel syndrome (IBS)

Protocol summary

Study aim

The aim of this study was to evaluate the effect of duloxetine on quality of life and symptoms of IBS in patients referred to the gastrointestinal clinic of Rasoul Akram Hospital in 2018

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 60 patients.

Settings and conduct

This research is a clinical trial. Patients referred to the gastroenterology clinic of Hazrat Rasool Akram Hospital (PBUH) who were diagnosed with Irritable Bowel Syndrome (IBS) based on RoomIV criteria were included in the study. In this randomized, double-blind, placebo-controlled study, 60 patients were treated with duloxetine (30 mg / day) or placebo for 12 weeks, while both groups received 135 mg twice daily. Evaluation was performed using IBS severity index at the beginning and in weeks 4, 8 and 12. IBS (IBS-QOF) quality of life assessment was also performed initially, at weeks 4, 8 and 12.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients with irritable bowel syndrome, mild to moderate score (score less than 11) in the Anxiety and Depression Questionnaire. Exclusion criteria: Psychotic patients, bipolar disorder, obsessive-compulsive disorder, substance use in the last 6 months, dementia, suicidal idea،Taking psychotropic drugs in the last 2 weeks , Pregnancy and lactation, age of under 18 years old and over 65 years old digestive bleeding, Persistent vomiting, Persistent abdominal pain,Unexplained weight loss, Crohn's, celiac disease, colon cancer, seizures, hypertension, angle-closure glaucoma

Intervention groups

Intervention group: Duloxetine Control group: Placebo

Main outcome variables

Irritable bowel syndrome severity index score, quality of life score of patients with irritable bowel syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200928048862N1**
Registration date: **2020-10-16, 1399/07/25**
Registration timing: **retrospective**

Last update: **2020-10-16, 1399/07/25**
Update count: **0**

Registration date

2020-10-16, 1399/07/25

Registrant information

Name
Rouhallah Noorian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5554 9111

Email address
shahradnoorian2020@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-27, 1397/08/05

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

2018-10-27, 1397/08/05

Actual recruitment end date

2019-03-11, 1397/12/20

Trial completion date

2019-05-10, 1398/02/20

Scientific title

The effect of duloxetine in quality of life and symptoms of patients with irritable bowel syndrome (IBS)

Public title
The effect of duloxetine in quality of life and symptoms of patients with irritable bowel syndrome (IBS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with irritable bowel syndrome (IBS) Mild to moderate score (score less than 11) in the Anxiety and Depression Questionnaire.
Exclusion criteria:
Psychotic patients, bipolar disorder, obsessive-compulsive disorder, substance use in the last 6 months, dementia, suicidal idea Taking psychotropic drugs in the last 2 weeks Pregnancy and lactation age of under 18 years old and over 65 years old digestive bleeding Persistent vomiting Persistent abdominal pain Unexplained weight loss Crohn's, celiac disease, colon cancer, seizures, hypertension, angle-closure glaucoma,
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization based on a table of random numbers into two groups of intervention and control
Blinding (investigator's opinion)
Double blinded
Blinding description
This study was a double blind study in which in this study both patients and evaluators were blind of the used drug. The drugs were delivered to the patients by another person in similar packages marked with a code. In the end, the researcher evaluated the patients without knowing the type of used drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of medical Sciences
Street address
Iran university of Medical Sciences,between Fazlollah Nouri and Shahid Chamran,Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-10-28, 1397/08/06
Ethics committee reference number
Ir.IUMS.REC.1397.947

Health conditions studied

1

Description of health condition studied
Irritable Bowel Syndrome
ICD-10 code
k58.0
ICD-10 code description
Irritable Bowel Syndrome

Primary outcomes

1

Description
Severity index of irritable bowel syndrome
Timepoint
The severity of irritable bowel syndrome was measured at the beginning of the study and in the fourth, eighth and twelfth weeks.
Method of measurement
Severity index of irritable bowel syndrome,

2

Description
Score of quality of life
Timepoint
Patients' quality of life was measured at the beginning of the study and in the fourth, eighth and twelfth weeks
Method of measurement
Quality of Life Questionnaire in Patients with Irritable Bowel Syndrome

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One 30 mg duloxetine capsule per day from Tadbir Kalay Jam Pharmaceutical Company, along with 135 mg Mebeverine tablets, twice at day for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: placebo in the form of capsules, similar to duloxetine at a dose of 30 mg per day with 135 mg drug Mebeverine for 12 weeks, from Tadbir Kalay Jam Pharmaceutical Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان حضرت رسول اکرم(ص)
Full name of responsible person
Roohallah Noorian
Street address
Kargarnejad psychiatric hospital , Ghotbe Ravandi Bulvard.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
DrMehrdad Eftekhar
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Iran University ofMedical Sciences,, between Sheikh Fazlullah Nouri and Shahid Chamran,Shahid Hemmat Highway..
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iumspr@ums.ac.i
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
Rouhallh Noorian
Position
Non-faculty specialist physician
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
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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