

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Irritable Bowel Syndrome
ICD-10 code	k58.0
ICD-10 code description	Irritable Bowel Syndrome
Primary outcomes	
<u>1</u>	
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,
<u>2</u>	
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.

City

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Province

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8715973446

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Shahradnoorian2020@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

DrMehrdad Eftekhari

Street address

Iran University of Medical Sciences,, between Sheikh
Fazlullah Nouri and Shahid Chamran,Shahid Hemmat
Highway..

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1449614535

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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

Rouhallh Noorian

Position

Non-faculty specialist physician

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Rouhallah Noorian

Position

Non-faculty specialist physician

Latest degree

Specialist

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

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Rouhallah Noorian

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

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