# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jul 2026

## The effect of duloxetine on symptoms and quality of life in patients with irritable bowel syndrome with moderate to severe symptoms

## Protocol summary

**Study aim**
The effect of duloxetine on symptoms and quality of life in patients with irritable bowel syndrome with moderate to severe symptoms

**Design**
Clinical trial with control group with parallel, randomized, phase 3 groups on 40 patients A random number table was used for randomization.

**Settings and conduct**
This intervention is performed in Khorshid Hospital in Isfahan. Patients with irritable bowel syndrome are admitted and randomly divided. Intervention group, patients will receive duloxetine and the second group will receive a placebo. Before and one week after the interventions, the level of depression, anxiety and stress, as well as the quality of life of patients and the severity of their disease are measured by special questionnaires.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Men and women aged 18 to 65 years, diagnosis of irritable bowel syndrome by a gastroenterologist, moderate to severe symptoms, informed consent to participate in the study, no depressive disorders, bipolar disorder or Exclusion criteria: diagnosis of any organic disease, failure to take medication regularly, failure to complete a questionnaire, severe side effects, patient request to be excluded from the study

**Intervention groups**
Intervention group: Patients in this group will be treated with duloxetine daily at a target dose of 60 mg per day for three months. The severity of symptoms, quality of life and the level of stress, anxiety and depression of patients are measured by special questionnaires and by a gastroenterologist before and after the interventions and are compared with each other. Control group: Patients in this group will be given placebo capsules daily for three months. The mentioned factors of patients are and by a gastroenterologist before and after the interventions and are compared with each other.

**Main outcome variables**
Anxiety, depression and stress and quality of life

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20190404043159N1**
Registration date: **2020-09-18, 1399/06/28**
Registration timing: **prospective**

Last update: **2020-09-18, 1399/06/28**
Update count: **0**

**Registration date**
2020-09-18, 1399/06/28

**Registrant information**
**Name**
Mohammad Reza Sharbafchi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2020-10-15, 1399/07/24
**Expected recruitment end date**
2020-11-04, 1399/08/14
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of duloxetine on symptoms and quality of life in patients with irritable bowel syndrome with moderate to severe symptoms

**Public title**
Duloxetine and the symptoms and quality of life of patients with irritable bowel syndrome

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Men and women aged 18 to 65 years Diagnosis of irritable bowel syndrome by a gastroenterologist Moderate to severe symptoms Conscious consent to participate in the study Have a minimum literacy Absence of depressive disorders, bipolar disorder or psychotic disorders

**Exclusion criteria:**
Diagnosis of any organic disease Failure to take medication regularly Failure to complete the questionnaire Severe side effects Patient request to leave the study

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

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group . The researcher begins to read the numbers in a predetermined manner and the patients are divided.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Patients are blinded according to the intervention or control treatment groups of the type of drug used. Also, the drugs are prepared in separate containers with numbering and the nurse who used the drug for the patients has no information about its type. Patients are seen by a specialist doctor and evaluated for symptoms and quality of life. Doctors and health evaluators are also unaware of the type of medication used. After collecting information, it enters the software with numbering, and after performing statistical analysis and completing the work, the codes are determined. Until then, the data analyzer and the data safety and monitoring committee do not know the patient groups. .

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Isfahan University of Medical Sciences

**Street address**
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Approval date**
2017-05-28, 1396/03/07

**Ethics committee reference number**
IR.MUI.REC.1396.3.752

## Health conditions studied

### 1

**Description of health condition studied**
Irritable Bowel Syndrome

**ICD-10 code**
K58

**ICD-10 code description**
Irritable bowel syndrome

### 2

**Description of health condition studied**
Quality of life

**ICD-10 code**

**ICD-10 code description**

### 3

**Description of health condition studied**
Stress, anxiety and depression

**ICD-10 code**
F43.0

**ICD-10 code description**
Acute stress reaction

## Primary outcomes

### 1

**Description**
Quality of life score
**Timepoint**
Before and one week after interventions
**Method of measurement**
Quality of Life Questionnaire for Patients with Irritable Bowel Syndrome

### 2

**Description**
Anxiety, depression and stress score
**Timepoint**
Before and one week after interventions
**Method of measurement**
By The Depression, Anxiety, and Stress Scale – 21 (DASS-21) questionnaire

### 3

**Description**
Severity of symptoms
**Timepoint**
Before and one week after interventions
**Method of measurement**
Irritable Bowel Syndrome Symptoms Severity Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Patients in this group will be treated with duloxetine daily at a target dose of 60 mg per day for three months. The severity of symptoms, quality of life and the level of stress, anxiety and depression of patients are measured by special questionnaires and by a gastroenterologist before and after the interventions and are compared with each other.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Patients in this group will be given placebo capsules daily for three months. The severity of symptoms, quality of life and the level of stress, anxiety and depression of patients are measured by special questionnaires and by a gastroenterologist before and after the interventions and are compared with each other.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Khorshid Hospial
**Full name of responsible person**
Mohammad Reza Sharbafchi
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
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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**
Esfahan 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**
Esfahan University of Medical Sciences

**Full name of responsible person**
Mohammad Reza Sharbafchi

**Position**
Assistant professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Psychiatrics

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is 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**
Yes - There is a plan to make this available

**Title and more details about the data/document**
All data can be shared after people have requested.

**When the data will become available and for how long**
Six months after publishing the results

**To whom data/document is available**
Academic researchers

**Under which criteria data/document could be used**
Scientific uses

**From where data/document is obtainable**
Isfahan University of Medical Sciences website

**What processes are involved for a request to access data/document**
Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

**Comments**