

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Efficacy of duloxetine add on conventional treatment in inflammatory bowel disease patients, on depression, anxiety quality of life and severity of symptoms

#### Protocol summary

##### Summary

We assessed the efficacy of drug duloxetine or placebo on anxiety, depression, severity of symptoms and quality of life in patients with inflammatory bowel disease. Inclusion criteria include men and women age 18-65 years old who were diagnosed with inflammatory bowel disease with no flare up through past six months and exclusion criteria include lifetime bipolar, psychotic, or obsessive-compulsive disorder; substance use disorders, major depressive disorder or anxiety disorders in the past 6 months and treatment with any psychotropic medication within seven days of beginning of study. The 40 subjects were selected from patients who referred to gastrointestinal clinic of Alzahra Hospital (Isfahan, Iran) during 2013 to 2014. After screening the subjects were divided into two groups of duloxetine and placebo randomly. The study was performed in 12 weeks. In drug group, duloxetine started with 30 mg once a day for 1 week, and then 60 mg once a day for the next 11 weeks. In placebo group the subjects received placebo in the same form and packages as duloxetine. We assessed anxiety, depression, severity of symptoms and quality of life in subjects before and just after the treatment with Hospital Anxiety and Depression Scale, Lichtiger Colitis Activity Index and World Health Organization Quality of Life Instruments respectively.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201411127841N8**

Registration date: **2014-11-17, 1393/08/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-11-17, 1393/08/26

##### Registrant information

###### Name

Mohammad Reza Sharbafchi

###### Name of organization / entity

Psychiatric group, Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1222 2457

###### Email address

sharbafchi@resident.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-03-01, 1391/12/11

##### Expected recruitment end date

2014-03-01, 1392/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of duloxetine add on conventional treatment in inflammatory bowel disease patients, on depression, anxiety quality of life and severity of symptoms

##### Public title

Duloxetine add on conventional treatment in inflammatory bowel disease patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 18-65 years aged; current diagnosis of inflammatory bowel disease; having no flare up of disease through past six months. Exclusion criteria: any serious medical condition that may interfere with safe study participation; current lactation, pregnancy or inadequate contraception; current serious suicidal intention or plan; lifetime bipolar, psychotic, or obsessive-compulsive disorder; substance use disorders, major depressive disorder or anxiety disorders in the past 6 months; treatment with any psychotropic medication within seven days (or five medication half-lives) of beginning of study.

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences

##### Street address

Hezar jerib Street

##### City

Isfahan

##### Postal code

#### Approval date

2013-02-15, 1391/11/27

#### Ethics committee reference number

6/2133/ع

## Health conditions studied

### 1

#### Description of health condition studied

Inflammatory bowel disease

#### ICD-10 code

K50

#### ICD-10 code description

Crohn disease [regional enteritis]

### 2

#### Description of health condition studied

Inflammatory bowel disease

#### ICD-10 code

K51

#### ICD-10 code description

Ulcerative colitis

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

At screening and and after 12 weeks

#### Method of measurement

Hospital Anxiety and Depression Scale

### 2

#### Description

Anxiety

#### Timepoint

At screening and and after 12 weeks

#### Method of measurement

Hospital Anxiety and Depression Scale

### 3

#### Description

Severity of symptoms

#### Timepoint

At screening and and after 12 weeks

#### Method of measurement

Lichtiger Colitis Activity Index

### 4

#### Description

Quality of life

#### Timepoint

At screening and and after 12 weeks

#### Method of measurement

World Health Organization Quality of Life Instruments

## Secondary outcomes

### 1

#### Description

Vomiting

#### Timepoint

At screening and every 2 weeks up to 12 weeks

**Method of measurement**

History and Physical examination

**2**

**Description**

Drowsiness

**Timepoint**

At screening and every 2 weeks up to 12 weeks

**Method of measurement**

History and Physical examination

**3**

**Description**

Dyspepsia

**Timepoint**

At screening and every 2 weeks up to 12 weeks

**Method of measurement**

History and Physical examination

**4**

**Description**

Nausea

**Timepoint**

At screening and every 2 weeks up to 12 weeks

**Method of measurement**

History and Physical examination

**Intervention groups**

**1**

**Description**

Drug group: Duloxetine started with 30 mg once a day for 1 week, and then 60 mg once a day for the next 11 weeks.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: The subjects received placebo in the same form and packages as duloxetine for 12 weeks

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Gastrointestinal clinic of Alzahra Hospital

**Full name of responsible person**

Mohammad Reza Sharbafchi

**Street address**

Sofe Street

**City**

Isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences, Psychosomatic Research Center

**Full name of responsible person**

Dr Hamid Afshar

**Street address**

Shariati Street

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan University of Medical Sciences, Psychosomatic Research Center

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences, Department of Psychiatry

**Full name of responsible person**

Mohammad Reza Sharbafchi

**Position**

Psychiatrist

**Other areas of specialty/work**

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**Person responsible for scientific**

## **inquiries**

### **Contact**

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## **Person responsible for updating data**

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**Name of organization / entity**

Isfahan University of Medical Sciences, Department of  
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**Full name of responsible person**

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*