Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of doluxetine 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 flair 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 respectedly.

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 Univercity of Medical Sciences

Country

Iran (Islamic Republic of)

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

Public title

Doluxetine 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 flair 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/چ

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
Anxeity
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

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Associate Professor

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Person responsible for updating data

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Full name of responsible person
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Other areas of specialty/work

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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