Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of Fluoxetine on symptoms and quality of life of patients with moderate to sever irritable bowel syndrome in adults.

Protocol summary

Summary

The main target of the study is to determine and compare the effect of 20 and 40 milligrams Fluoxetine on symptoms and quality of life of patients with moderate to severe irritable bowel syndrome. 180 Patients with moderate to severe irritable bowel syndrome who refer to Poursinay Hakim clinic of Isfahan will be recruited if meet the eligibility criteria. The patients will be randomly assigned into one of the following groups to receive 20 mg Fluoxetine daily, 40 mg Fluoxetine daily, or placebo for 12 weeks. The severity of symptoms, quality of life, anxiety, and depression will be measured at the baseline and 4th and 12th week after the intervention. Symptoms will also be registered daily. The follow-up period will be 6 month and the outcomes will also be measured every 3 months during this period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805012159N2**
Registration date: **2010-05-29, 1389/03/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-05-29, 1389/03/08

Registrant information

Name

Forugh Ghaedi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Fluoxetine on symptoms and quality of life of patients with moderate to sever irritable bowel syndrome in adults.

Public title

Evaluating the effect of Fluoxetine on symptoms and quality of life of patients with moderate to severe irritable bowel syndrome in adults.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 years, IBS diagnosis through ROME II criteria, moderate to severe symptoms through severity of symptom questionnaire Exclusion criteria : Diagnosis of any organic disease related to symptoms during the study, psychological disorders Taking any other psychotropic drugs at the beginning or during the trial or taking a MAO-inhibitor drugs during 2 weeks before entering to the trial, record of taking Fluoxetine for treatment of IBS in the past, Presence of any contraindications for taking Fluoxetine, low compliance,

severe complications due to Fluoxetine, Pregnancy or breastfeeding at the beginning or during the trial

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **180**

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

Street address
Isfahan University of Medical Sciences - Azadi square - Isfahan

City
Isfahan

Postal code

Approval date
2010-04-25, 1389/02/05

Ethics committee reference number
288243

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome

ICD-10 code
K58

ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Severity of symptom

Timepoint
Baseline - end of the 4th and 12th week of the intervention and 3 and 6 month after the end of the study

Method of measurement
IBS-SSS questionnaire

2

Description
Quality of life

Timepoint
baseline, end of the 4th and 12th week of the intervention and 3 and 6 month after the end of the study

Method of measurement
IBS quality of life questionnaire (IBS-QOL)

Secondary outcomes

1

Description
Depression

Timepoint
Baseline - end of the 4th and 12th week of the intervention and 3 and 6 month after the end of the study

Method of measurement
Hospital anxiety and Depression questionnaire

2

Description
Anxiety

Timepoint
Baseline - end of the 4th and 12th week of the intervention and 3 and 6 month after the end of the study

Method of measurement
Hospital anxiety and Depression questionnaire

Intervention groups

1

Description
Fluoxetine 20 milligram, capsule, daily plus placebo capsule, oral, daily for 12 weeks

Category
Treatment - Drugs

2

Description
2 placebo capsules, oral, daily for 12 weeks

Category
Placebo

3

Description
Fluoxetine, 40 milligram, 20 miligram capsules twice daily, oral, for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Research-Therapeutical Institution of Poursina Hakim
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Vice Chancellery for Research of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences - Azadi square- Isfahan
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
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
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Forugh Ghaedi
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Person responsible for updating data

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Web page address

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