

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of Fluoxetine Therapeutic Effects With Duloxetine in patients with IBS with constipation

Protocol summary

Constipation, abdominal pain , life quality, Flatulence

Study aim

Comparison of the therapeutic effects of Fluoxetine with Duloxetine in patients with IBS type of constipation

Design

Randomized clinical trial, single central, parallel with three groups

Settings and conduct

Patients with Irritable bowel syndrome in the age range of 18-45 years who have predominant constipation symptoms and in accordance with Rome2 criteria are diagnosed by gastroenterologist and general specialist from among the referrals to the gastroenterology clinic and general, and all patients Must lack warning signs including diarrhea, weight loss, gastrointestinal bleeding, and the use of drugs, alcohol and drugs. In some cases, patients in any biopsy or physical examination have any symptoms of organic disease, they are excluded from the study

Participants/Inclusion and exclusion criteria

Patients are newly diagnosed with irritable bowel syndrome. People are between the ages of 18-45 who have predominant constipation symptoms and are in accordance with Rome2 criteria. All patients should have no warning signs including diarrhea, weight loss, gastrointestinal bleeding, and the use of drugs, alcohol and drugs. In some cases, patients in any biopsy or physical examination have any signs or symptoms of organic disease, are excluded

Intervention groups

Then, in the first group, dicyclomine is given with fluoxetine 20 mg and the second group is dicyclomine and duloxetine 20 mg and the third group is given only the dicyclomine. Then the questionnaire will be filled by the researcher for them and the patients will be followed up monthly in person and by the phone for two consistent months. The symptoms will be divided by severity into 4 groups, which gives 25 grades to each group.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171115037478N1**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **retrospective**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Behnam Sajedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 2928

Email address

behnamsajedi1365@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-21, 1396/08/30

Expected recruitment end date

2018-01-19, 1396/10/29

Actual recruitment start date

2017-06-21, 1396/03/31

Actual recruitment end date

2017-09-20, 1396/06/29

Trial completion date

empty

Scientific title

Comparison of Fluoxetine Therapeutic Effects With Duloxetine in patients with IBS with constipation

Public title

Fluoxetine Therapeutic Effects With Duloxetine in patients with IBS with constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

new cases of irritable bowel syndrome aged 18-45 constipation predominant symptoms consistent with the criteria Rome2 criteria

Exclusion criteria:

patients with night diarrhea patients with weight loss patients with history of GI bleeding patients that use alcohol, drugs and opioms. patients with psychological diseases patients with CNS disorders patients with kidney or liver failure cardica patients

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **162**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of selecting individuals and their placement in triple groups will be randomized, so that after confirmation of the conditions necessary for inclusion in the study patients will be selected sequentially and the first patient in the first group, the second patient in The second group and the third patient will be placed in the third group, and in the same way, again, the groups will take each patient in order to reach the desired level

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences Ethics Committee

Street address

Khorramshahr Street

City

Zanjan

Province

Zanjan

Postal code

۴۵۱۵۶۱۳۱۱۳

Approval date

2017-08-07, 1396/05/16

Ethics committee reference number

ZUMS.REC.1396.93

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome is a type of constipation

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Severity of illness in irritable bowel syndrome, constipation type

Timepoint

At the beginning of the study and two months later

Method of measurement

IBS-SSS(IBS-(Severity scoring system)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The first group of dicyclomin tablets is given every 8 hours with fluoxetine 20 mg daily for 2 months

Category

Treatment - Drugs

2

Description

Intervention group 2: The second group of dicyclomine tablets is given every 8 hours with duloxetine 20 mg daily for 2 months.

Category

Treatment - Drugs

3

Description

Intervention group 3: The third group of dicyclomine tablets is given every 8 hours 20 mg daily for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital in Zanjan

Full name of responsible person

Sattar Jafari

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Dr. Shariati Street

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Behnamsajedi1365@zums.ac.ir

Web page address

http://Zums.ac.ir/index.php?slc_lang=fa&sid=9

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

Street address

Khorramshahr Street

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Web page address

http://Zums.ac.ir/index.php?slc_lang=fa&sid=3&slct_pg_id=2089

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Behnam sajedi

Position

Resident of Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Shariati St., Valiasr Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Behnam Sajedi

Position

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Resident of Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Shariati St., Valiasr Hospital

City

Zanjan

Province

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