

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effectiveness of memantine in patients with Irritable Bowel Syndrome treated with doxepin in quality of life, pain and cognition of ;A double- Blinded Controlled Clinical Trial

Protocol summary

Study aim

Investigating the effect of doxepin and memantine on the quality of life, pain and cognitive status of IBS patients Comparison of cognitive score, pain intensity and quality of life in the studied groups. Comparison of demographic characteristics before the intervention in the studied groups

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. The rand function of Excel software was used for randomization.

Settings and conduct

This clinical trial will be conducted at Imam Ali Yaz Clinic. The doctors are given a pre-coded table of numbered numbers and the patients are entered into the study in the order of the table numbers. Also, the pills are removed from the blister and placed in a separate envelope that has a code, and the pills, in terms of shape, The color and size are the same, so the present study is double-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 25-65 years, who have experienced symptoms for at least three days a week, and more than a year has passed since the onset of their symptoms. Not taking antidepressants, cardiovascular drugs and corticosteroids Exclusion criteria: history of psychotic, bipolar, obsessive compulsive disorders, history of moderate to severe major depression or substance abuse in 6 Last month, patients with suicidal thoughts and attempts and...

Intervention groups

Patients in the first group receive 25 mg of doxepin capsules daily for the first week and then 50 mg along with memantine 5 mg daily for the first month and then 10 mg of Tapain for 12 weeks. Patients in the second group receive 25 mg of doxepin capsules daily for the

first week and then 50 mg and placebo for 12 weeks.

Main outcome variables

Quality of life score in IBS-QOL questionnaire Pain score in the questionnaire (2-SF-MPQ) Cognitive disorders score in MMSE questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N14**
Registration date: **2022-12-11, 1401/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-11, 1401/09/20**

Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Mohsen Zabihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3865

Email address

mzabihi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of memantine in patients with Irritable Bowel Syndrome treated with doxepin in quality of life, pain and cognition of ;A double- Blinded Controlled Clinical Trial

Public title

The effectiveness of memantine in patients with Irritable Bowel Syndrome treated with doxepin in quality of life, pain and cognition of ;A double- Blinded Controlled Clinical Trial

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

25-65-year-olds who have been experiencing symptoms for more than a year since the onset of symptoms and experiencing symptoms for at least three days a week
Not taking antidepressants
Not taking cardiovascular drugs
No use of corticosteroids.

Exclusion criteria:

One of the side effects of memantine is diarrhea, the prevalence of which is low, mild and transient, but if the patient does not tolerate it, the person will be excluded from the study. History of psychotic disorders, bipolar disorders, obsessive compulsive disorders, history of moderate to severe major depression or drug abuse in the last 6 months. Patients with suicidal thoughts and attempts. People who are pregnant or planning to become pregnant and nursing mothers
Severe underlying disease
History of significant weight loss (5% of body weight in six months)
Gastrointestinal bleeding
Patients with cardiovascular and respiratory diseases, diabetes, hyperthyroidism
Liver disorders, seizures
Urinary retention, benign prostate enlargement
Allergy to any of the drugs used
Aggravation of the disease during the study

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to variable blocks using random blocks of 4 in two groups 35 people are subjected to intervention and control. Randomization will

be done using the software randomization option in Excel. accidental process Randomization is done by the study methodology consultant and the clinical researchers are not aware of the randomization process. After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

To doctors table Pre-coded numbered numbers are given and the patients are included in the study in the order of the table numbers. Also, the pills are The blisters are removed and placed in a separate envelope that has a code and the pills are the same in terms of shape, color and size, so the present study is double-blind.

Placebo

Used

Assignment

Parallel

Other design features

This clinical trial will be conducted after considering the inclusion and exclusion criteria of the study on 70 patients aged 25 to 65 years, and the clinical diagnosis of IBS will be based on clinical evidence, colonoscopy and using IV Rome criteria by a specialist doctor. The patients will be randomly divided into two intervention groups including doxepin and memantine and the control group including doxepin and placebo randomly using the RAND function (Excel software) in one of the two divided groups (35 people in each group). The month after the start of the treatment will be followed up and the criteria of the study will be recorded. This study is a prospective and double-blind randomized controlled clinical trial and will be conducted on 70 patients who will be randomly assigned to two 35-person control or intervention groups.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Faculty of Pharmacy and Pharmaceutical Sciences, Tehran Islamic Azad University

Street address

the second alley on the left-Khamenei 5 - Khamenei Blvd

City

Yazd

Province

Yazd

Postal code

8915145202

Approval date

2022-10-16, 1401/07/24

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrome(IBS)

ICD-10 code

K58.3

ICD-10 code description

Irritable bowel syndrome with mixed bowel habits [IBS-M]

Primary outcomes

1

Description

Quality of life score in IBS-QOL questionnaire in 70 patients with irritable bowel syndrome

Timepoint

At the beginning of the study and 1, 2, and 3 months after starting to take drugs (doxepin alone or doxepin and memantine together)

Method of measurement

Quality of life questionnaire for irritable bowel syndrome patients (IBS-QOL)

2

Description

Pain score in questionnaire (SF-MPQ-2) in 70 patients with irritable bowel syndrome

Timepoint

At the beginning of the study and 1, 2, and 3 months after starting to take drugs (doxepin alone or doxepin and memantine together)

Method of measurement

McGill Pain Questionnaire (2-SF-MPQ)

3

Description

Cognitive disorders score in MMSE questionnaire in 70 patients with irritable bowel syndrome

Timepoint

At the beginning of the study and 1, 2, and 3 months after starting to take drugs (doxepin alone or doxepin and memantine together)

Method of measurement

Short Mental State Test Questionnaire (MMSE)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group :patients in the first group, 25 mg of doxepin capsules daily for the first week and then 50 mg (25 mg capsules twice a day) orally for 12 weeks along with memantine 5 mg daily for the first month and then 10 mg grams orally for 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in the second group receive 25 mg of doxepin capsules daily for the first week and then 50 mg (twice a day of 25 mg capsules) and placebo orally for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emma Ali Clinic

Full name of responsible person

Dr.Reza Bidaki

Street address

Imam Ali Clinic- Nawab Boulevard - Yazd

City

Yazd

Province

Yazd

Postal code

8915145202

Phone

+98 35 3630 1700

Email

Reza_bidaki@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zahra Mousavi

Street address

Faculty of Pharmaceutical Sciences-Yakhchal St.- Qolhak

City

Tehran

Province

Tehran

Postal code

1941933111

Phone

+98 21 2264 0052

Fax

Email

jafariazar.z@iaups.ac.ir

Web page address

https://tms.iau.ir

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

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Maedeh Heydari

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

the second alley on the left-Khamenei 5 - Khamenei Blvd

City

yazd

Province

Yazd

Postal code

8915145202

Phone

+98 35 3521 1206

Email

maedeh73heydariy@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mohsen Zabihi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Alem sq.

City

Yazd

Province

Yazd

Postal code

8915145202

Phone

+98 35 3820 3865

Fax**Email**

mzabihi100@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Maedeh Heydari

Position

University student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

the second alley on the left-Khamenei 5 - Khamenei Blvd

City

Yazd

Province

Yazd

Postal code

8915145202

Phone

+98 35 3521 1206

Email

maedeh73heydariy@yahoo.com

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