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 studiedgroups. 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 corticosteroidsExclusion 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

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Iran (Islamic Republic of)

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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
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Yazd
Province
Yazd
Postal code
8915145202
Approval date
2022-10-16, 1401/07/24
Ethics committee reference number

IR.IAU.PS.REC.1401.296

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
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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
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Full name of responsible person
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Position
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Latest degree
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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