

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Efficacy of Memantine augmentation in moderate to severe obsessive-compulsive symptoms

#### Protocol summary

##### Study aim

Efficacy of memantine add-on to standard treatment of obsessive-compulsive disorder

##### Design

Randomized double-blind phase 3 clinical trial on 30 patients allocated to treatment groups by permuted block randomization with quadruple blocks

##### Settings and conduct

double-blind clinical trial on patients with moderate to severe obsessive-compulsive disorder at Kargarnezhad Hospital Clinic in Kashan, Iran. The psychiatrist responsible for the project and the executors and patients and the personnel distributing the medicine will be blind to the contents of the sealed packages of the medicine and the placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Age: 18-60 years 2-Patients with obsessive-compulsive disorder based on Yale Brown scale and clinical interview based on DSM5 criteria. 3- Yale Brown score is greater than or equal to 15 4. No comorbid psychiatric disorder based on DSM5 5 - Do not have systemic diseases 6. Do not consume alcohol and substances 7. Receive informed consent 8. Not receiving psychotropic treatment for 6 weeks before screening  
Exclusion criteria: 1- Pregnancy and lactation in women of childbearing age or not having a safe method of contraception 2. Psychiatric disorders based on DSM5 3- Simultaneous somatic treatment 4-Simultaneous treatment with any other medicine 5. Receiving psychotropic treatment from 6 weeks before screening 6- Receiving any method of psychotherapy 7. History of memantine use 8- Patient's desire to leave the study

##### Intervention groups

Two 15 member groups, in the first group, memantine and sertraline tablets are given for 8 weeks, and in the second group, placebo and sertraline are given.

##### Main outcome variables

YBOC score, YBOC obsession subscale, YBOC compulsion subscale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201227049851N1**

Registration date: **2021-03-07, 1399/12/17**

Registration timing: **prospective**

Last update: **2021-03-07, 1399/12/17**

Update count: **0**

##### Registration date

2021-03-07, 1399/12/17

##### Registrant information

##### Name

Atefeh Sattarinezhad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 2332 5453

##### Email address

sattarinezhad-a@kaums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-03-15, 1399/12/25

##### Expected recruitment end date

2021-04-20, 1400/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of Memantine augmentation in moderate to severe obsessive-compulsive symptoms

#### Public title

"Efficacy of Memantine Add on Treatment in Obsessive Compulsive Disorder"

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

All patients who suffer from obsessive-compulsive disorder according to DSM V and clinical interview. Patients who have Yale-Brown Scores of 15 and above. Patients who give written consent for participating in the study.

##### Exclusion criteria:

Patients who are diagnosed with a comorbid DSM V psychiatric diagnosis. Patients who suffer from any systemic disease such as diabetes, hypo and hyperthyroidism, hypertension, hepatic failure or renal failure. Patients who use alcohol or any other substance. Patients who have received a psychotropic medicine during the last 6 months. Women who are pregnant or breastfeeding or do not use any certain contraceptive method. Patients who use concomitant somatic treatments. Patients who are under treatment with Acetyl Cysteine, buprenorphine or any other medicine. Patients who receive any kind of psychotherapies.

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The method of assigning treatment is permuted block randomization with quadruple blocks according to the random number table. Thus, by collecting each qualified quadruple block, one of the serials AABB, ABAB, BAAB, BABA, BBAA, ABBA is randomly assigned to the items within each block. The serials were made according to the permutation formula  $P(x, y, z) = P(x) \times P(Y) \times P(Z)$ , which for a block of 4, the number of permutations of the possible combination is  $4! / 2! \times 2! = 6$  was obtained and probable sequences were made to its number based on it. Consequently, according to the so called instructions, the patient will be stratified into one of the groups A or B. The drugs prepared under the label A or B are mixed in a carton and provided to the project implementers.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The placebo prepared by Kashan University of Medical Sciences and the memantine tablet produced by Darupakhsh Company are prepared in the similar gelatin capsule coating in terms of appearance, size and color and taste, in matched and sealed packages. Sertraline produced by Sobhan Daroo Company is also provided by the project executors given to the patients. Drug distribution is done by a staff member of the clinic of Kargarnezhad Hospital who has not participated in any of the steps of preparation, packaging and coding. The distribution of medicine is done in 0,1,2 weeks and then once every two weeks at the so-called clinic.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

###### Street address

Kashan University of Medical Sciences, Qotb Ravandi Blvd.

###### City

Kashan

###### Province

Isfahan

###### Postal code

73474-87159

##### Approval date

2021-02-24, 1399/12/06

##### Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.238

### Health conditions studied

#### 1

##### Description of health condition studied

Obsessive-compulsive disorder

##### ICD-10 code

F42

##### ICD-10 code description

Obsessive-compulsive disorder

### Primary outcomes

## 1

### Description

Yale Brown Score

### Timepoint

Weeks 0,2,4,8

### Method of measurement

Yale Brown Scale questionnaire

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group :15 male and female patients between the ages of 18 and 60 years who have moderate to severe obsessive-compulsive disorder based on DSM V-based clinical interview and Yale Brown test score will be treated with treated with Sobhan Daru Company's Sertraline tablets and Daroo Pakhsh Memantine tablets. Sertraline tablets will be started with a daily dose of 50 mg and the dose is increased 50 milligrams every week up to 200mgs and continued until the end of the eighth week. Memantine tablets in a placebo-like gelatin coating will be started at 5 mg daily and increased to 10 mg daily at the end of the first week and continued at the same dose until the end of week 8. Patients will be visited in weeks 0, 1, 2, 4, and 8 and the Yale Brown questionnaire and the side effects checklist will be completed.

### Category

Treatment - Drugs

## 2

### Description

Control group: 15 male and female patients between 18 and 60 years of age with moderate to severe obsessive-compulsive disorder according to a DSM V based clinical interview and a Yale Brown questionnaire will be treated with Sertraline tablets of Sobhan Daru Company and the placebo prepared by Kashan University of Medical Sciences in similar gelatin capsule coatings for 8 weeks. Sertraline tablets produced by Sobhan Daru Company will be initiated with a dose of 50 mgs. The dose will be increased by 50 mgs every week up to 200 mg until the end of week 8. At the same time, patients will receive a placebo( Darupakhsh 1 mg tablet) containing gelatin capsule once a day from week 0 to the end of week 8.They will be visited in weeks 0, 1, 2, 4, and 8 and the Yale Brown questionnaire and the side effects checklist will be completed at weeks 0,2,4,8.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Kargarnezhad hospital clinic,Kashan

#### Full name of responsible person

Atefeh Sattarinezhad

#### Street address

Kargarnezhad Hospital,Qotb Ravandi Blvd

#### City

کاشان

#### Province

Isfahan

#### Postal code

8715973446

#### Phone

+98 31 5554 9111

#### Email

sattarinezhad-a@kaums.ac.ir

#### Web page address

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Hamid Reza Banafsheh

#### Street address

Kashan University of Medical Sciences,Qotb Ravandi BLvd

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715988141

#### Phone

+98 31 5554 2999

#### Fax

+98 31 5557 5057

#### Email

banafshe57@hotmail.com

#### Web page address

<http://research.kaums.ac.ir/Default.aspx?PageID=58>

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Kashan University of Medical Sciences

### Proportion provided by this source

10

### 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Atefeh Sattarinezhad

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kargarnezhad hospital ,Qotb Ravandi Blvd.

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715973446

**Phone**

+98 31 5554 9111

**Fax**

+98 31 5554 0036

**Email**

sattarinezhad-a@kaums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zahra Sepehrmanesh

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kargarnezhad hospital,Qotb Ravandi Blvd.

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715973446

**Phone**

+98 31 5554 9111

**Email**

sepehrmanesh\_z@kaums.ac.ir

**Web page address**

[http://pajouhan.kaums.ac.ir/webdocument/load.action?webdocument\\_code=8000&masterCode=17000101](http://pajouhan.kaums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=17000101)

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zahra Sepehrmanesh

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kargarnezhad hospital,Qotb Ravandi Blvd

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715973446

**Phone**

+98 31 5554 9111

**Email**

sepehrmanesh\_z@kaums.ac.ir

**Web page address**

<http://kargarnejad.kaums.ac.ir/Default.aspx?PageID=48>

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Demographic characteristics of subjects, raw scores of Yale Brown tests, checklist of side effects

**When the data will become available and for how long**

Access period starts one year after the results are published

**To whom data/document is available**

Researchers working for academic and scientific institutes

**Under which criteria data/document could be used**

For metaanalyses and systematic reviews and head to head studies

**From where data/document is obtainable**

Research Center of the Vice Chancellor for Research of Kashan University of Medical Sciences

**What processes are involved for a request to access**

**data/document**

Sending a request letter to the Vice Chancellor for  
Research of Kashan University of Medical Sciences

approved by the supervisor attending of the project

**Comments**