

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect and no effect of augmentation of Gabapentin and Memantine with Selective Serotonin Reuptake Inhibitors (SSRIs) in treatment of patients with Obsessive Compulsive Disorder (OCD).

#### Protocol summary

##### Summary

This study will be done to effect and no effect of augmentation of Gabapentin and Memantine with Selective Serotonin Reuptake Inhibitors (SSRIs) in treatment of patients with Obsessive Compulsive Disorder (OCD). The present research is a double blind clinical trial. The study sample population is consist of all patients referring to the addiction treatment center of Farabi Hospital in Kermanshah, which 75 of them will be selected by census method, and in accidental method in three groups of 25 will be replaced and Obsessive-compulsive Scale Yale - Brown (YBOCS) will be distributed among them. The first group, SSRI drugs included fluoxetine with placebo, the second group SSRI drugs with Gabapentin and the third group SSRI drugs with Memantine that each will receive daily for 8 weeks. SSRI drugs with dose of 20 mg, Gabapentin with dose of 150 mg and Memantine with dose of 5 mg will start. And in the fourth week which will be re-examined if the dissatisfaction of patients in reducing the symptoms Fluoxetine dose can be 40 to 60 mg and dose of Gabapentin 600 to 900 mg and Memantine to 10 mg will be increased. The questionnaire will be re-distributed among three groups at the first, 4 weeks later, and at the end of the study (8 weeks after the start of the study), and the severity of obsessive-compulsive disorder will be measured. Inclusion criteria included a diagnosis of obsessive-compulsive disorder according to the DSM-5 and a history of drug allergy to SSRI's, Memantine or Gabapentin were Exclusion criteria.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062623705N6**  
Registration date: **2016-07-03, 1395/04/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-07-03, 1395/04/13

##### Registrant information

###### Name

Mostafa Alikhani

###### Name of organization / entity

Kermanshah University of Medical Sciences -  
Substance Abuse Prevention Research Center

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research Affairs, Kermanshah  
University of Medical Sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect and no effect of augmentation of Gabapentin

and Memantine with Selective Serotonin Reuptake Inhibitors (SSRIs) in treatment of patients with Obsessive Compulsive Disorder (OCD).

#### Public title

The effect of augmentation of Gabapentin and Memantine with Selective Serotonin Re uptake Inhibitors (SSRIs) in treatment of patients with Obsessive Compulsive Disorder (OCD).

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of obsessive-compulsive disorder according to the DSM-5 by psychologist; patients that their first reference for treatment or at least one month from cutting drug treatment is passed; Age range 20-40 years. Exclusion criteria: History of organic disease Seizures, diabetes, liver or kidney failure, hypothyroidism; Concomitant use of cardiac medications, Blood pressure, hormones, thyroid; Having other major psychiatric disease and substance abuse; Medical allergy to SSRI, Memantine with Gabapentin; Unwillingness participate in the study; Require hospitalization or receive ECT.

#### Age

From **20 years** old to **40 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **75**

#### 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

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

#### City

Kermanshah

#### Postal code

#### Approval date

2016-05-11, 1395/02/22

#### Ethics committee reference number

kums.rec.1395.86

## 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

obsessive-compulsive disorder

#### Timepoint

The beginning of the study (baseline), week four and end of the study (week eight)

#### Method of measurement

Based on the severity of obsessive-compulsive disorder

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the experimental group 1, the participant will receive a SSRI drugs with Memantine (SSRI with a dose of 20 mg, Memantine 5 mg) daily. then questionnaire will be redistributed at baseline,4 weeks later, and at the end of the study (8 weeks after the start of the study), and the severity of obsessive-compulsive disorder will be measured

#### Category

Treatment - Drugs

### 2

#### Description

In the control group, the participant will receive a SSRI drugs include Fluoxetine with placebo(Fluoxetine40 to 60 mg ) daily,then the questionnaire will be re-distributed at the baseline, 4 weeks later, and at the end of the study (8 weeks after the start of the study), and the severity of obsessive-compulsive disorder will be measured.

#### Category

Placebo

### 3

#### Description

In the experimental group 2, the participant will receive a SSRI drugs with Gabapentin (SSRI with a dose of 20 mg, Gabapentin150 mg) daily. then questionnaire will be redistributed at baseline,4 weeks later, and at the end of the study (8 weeks after the start of the study), and the severity of obsessive-compulsive disorder will be measured.

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

**Name of recruitment center**

Farabi Hospital

**Full name of responsible person**

Dr. Jalal Shakeri

**Street address**

Isar square, Farabi Hospital

**City**

Kermanshah

### Sponsors / Funding sources

#### 1

##### Sponsor

**Name of organization / entity**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences , Kermanshah Unvers

**Full name of responsible person**

Koroush Hamzehee

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

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

Yes

**Title of funding source**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences , Kermanshah Unvers

**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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Haniyeh Gharehbaghi

**Position**

Psychiatrist

**Other areas of specialty/work****Street address**

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### Person responsible for scientific inquiries

#### Contact

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### Person responsible for updating data

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**Full name of responsible person**

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**Position**

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## 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*