

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Name of organization / entity

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Substance Abuse Prevention Research Center

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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 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, Gabapentin 150 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 University

Full name of responsible person

Korosh Hamzehee

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

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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

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

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

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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