Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

+98 838264513

Email address

mo.alikhani@kums.ac.ir

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 Univers

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 Univers

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
Isar square, Farabi Hospital

City
Kermanshah

Postal code

Phone
+98 83 3827 6683

Fax

Email
b.rahami2556@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Vahid Farnia

Position
Psychiatrist

Other areas of specialty/work

Street address
Isar square, Farabi Hospital

City
Kermanshah

Postal code

Phone
+98 83 3826 4513

Fax

Email
vfarnia@yahoo.com

Web page address

Person responsible for updating data

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
Isar square, Farabi Hospital

City
Kermanshah

Postal code

Phone
+98 83 3827 6683

Fax

Email

b.rahami2556@gmail.com

Web page address

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