

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Pregabalin augmentation in treatment resistant obsessive compulsive disorder:a randomized double blind controlled clinical trial

Protocol summary

Study aim

Assessing effect of pregabalin in resistant OCD

Design

According table of randomization patients divided to two groups and patient and the person that do intervention (Yale brown) are blind.

Settings and conduct

Patients who are chosen by random table divided to two group (without know about kind of group) before start intervention done yale brown scale by a staff that don not know about the group of patients. After that one group get pregabalin another group get placebo. After 12 weeks done yale brown scale too.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient with impression of OCD according to DSM V; Yale brown scale>15; without any other psychiatric problem except OCD; without medical problem; do not use any substance Exclusion criteria: pregnancy; lactation; during psychotherapy

Intervention groups

The patients are divided into two groups that half of them receive pregabalin and the other group take placebo.

Main outcome variables

Assese severity of obsession and compulsion with yale brown scale after get pregabalin.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181225042113N1**

Registration date: **2019-03-05, 1397/12/14**

Registration timing: **retrospective**

Last update: **2019-03-05, 1397/12/14**

Update count: **0**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name

Mehrnoosh Ghaedsharaf

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3226 1574

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

empty

Trial completion date

2019-06-22, 1398/04/01

Scientific title

Pregabalin augmentation in treatment resistant obsessive compulsive disorder:a randomized double blind controlled clinical trial

Public title

Pregabalin augmentation in treatment resistant obsessive compulsive disorder:a randomized double blind controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with impression of OCD according to DSM-V Yale brown scale > 15 Without any other psychiatric problem except OCD Patient without medical problem Do not use any substance

Exclusion criteria:

Pregnancy Lactation During psychotherapy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random numbers; according to table of random numbers and number of patient that come to clinic chose patient for study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the people that done Yale brown are blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand ave.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2018-12-24, 1397/10/03

Ethics committee reference number

Ir. Sums. Med. Rec. 1397.395

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

Number of yale brown scal

Timepoint

Before give pregabalin and after 12 week done yale brown scale

Method of measurement

Yale brown scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group :continue get serteralin and add pregabalin (start with 75mg and slowly increase to 150mg for 12weeks. We assese numbers of yale brown scale by paired T test.

Category

Treatment - Drugs

2

Description

Control group: Control group :continue get serteraline like first group and (instaed of pregabal) get placebo. Before start study and also the end of study all patients fill yale brown scale.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Hafez hospital

Full name of responsible person

Dr Arash Mowla

Street address

Hafez hospital, Abiverdi Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
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
Shiraz University of Medical Sciences
Full name of responsible person
Mehrnoosh Ghaedsharaf
Position
Resident of psychiatry
Latest degree
Medical doctor
Other areas of specialty/work

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Person responsible for updating data

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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

Data just available for professor in university

When the data will become available and for how long

Starting 1 year after publication

To whom data/document is available

Reasercher in university

Under which criteria data/document could be used

By e mailing the request data is available for reasercher

From where data/document is obtainable

Mehrghardsharaf@gmail. Com

What processes are involved for a request to access data/document

After evaluate request by authers during 1 month data is available

Comments