Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Mirtazapine Augmentation in Resistant Obsessive Compulsive Disorder:a Double Blind Placebo Controlled Clinical Trial

Protocol summary

Study aim
Treatment of obsessive thoughts and actions that led to the patient's dysfunction

Design
The sample is performed on 60 patients with refractory obsessive-compulsive disorder who treated with sertraline (at least 6 weeks with sufficient dose) with no response. Patients in a completely random (coin toss) thirty people in the placebo group Thirty people in the control group. Mirtazapine and placebo in unnamed and similar packages and patients do not know the contents of the packages. The examiner does not know about the medicine used by patients and the contents of the packages

Settings and conduct
Referrals to the psychiatric clinic of Hafez Hospital in Shiraz who have taken sertraline. All patients admitted to the yale-brown obsessive compulsive scale(Y-BOCS) study will be taken. People receive a placebo that is similar in appearance. After receiving 12 weeks of treatment, the Y-BOCS test is performed again. Finally, the reduction in Y-BOCS score in patients in the two groups is compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria:People who have been diagnosed with obsessive -compulsive disorder based on DSM5.People with a yale-brown obsessive compulsive scale above 15.Has an age range of 18 to 60 years. Exclusion criteria:Pregnant and lactating women. People who are undergoing psychotherapy. Physical illness (liver problem, kidney problem, thyroid problem, respiratory problem). They have other psychiatric problems: According to DSM 5 criteria, psychotic disorder, anxiety disorder, dementia, mood disorder. Mental retardation. Consumption of drugs or alcohol

Intervention groups
Randomly given to two groups of 30 patients receiving mirtazapine and 30 receiving placebo,both are similar in appearance.

Main outcome variables
Check the severity of symptom (obsessive thoughts;obsessive behavior;Dysfunction)

General information

Reason for update

Acronym
مطالعه روان پزشکی شیراز

IRCT registration information
IRCT registration number: **IRCT20201004048919N1**
Registration date: **2021-05-11, 1400/02/21**
Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**
Update count: **0**

Registration date
2021-05-11, 1400/02/21

Registrant information

Name
Haniyeh Baniasadipur

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 4434 0424

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h.baniasadipour@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-21, 1400/04/30

Expected recruitment end date
2021-09-21, 1400/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Mirtazapine Augmentation in Resistant Obsessive Compulsive Disorder:a Double Blind Placebo Controlled Clinical Trial

Public title
Mirtazapine Augmentation in Resistant Obsessive Compulsive Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
people who have been diagnosed with obsessive - compulsive disorder based on DSM5. People with a yale-brown obsessive compulsive scale above 15. Has an age range of 18 to 60 years.
Exclusion criteria:
Pregnant women and breastfeeding People receivinig psychotherapy. having major physical illnesse: liver problems (they have high liver enzymes),kidney problems(BUN ,CR are high), thyroid problem, trouble breathing. They have other psychiatric problems: According to the DSM5 criteria, they have psychotic disorder, anxiety disorder, dementia, mood disorder, and mental retardation. use drugs or alcohol
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

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
patients are randomly (Flip the coin) 30 people in the placebo group and 30 people in the control group. Mirtazapine and placebo packaged in unnamed packages with the same name,and patients do not know about the patients medication and the contents of the packages.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blind.In this way, The patient and the relevant psychologist are unaware of whether the person is in the control or case group to perform the test.
Placebo
Used
Assignment
Parallel
Other design features
Due to the high prevance of OCD disease ,its effect on the patients interpersonal and occupational relationships to prevent wasting patients time requires the use of augmentation therapy strategy to help patients recover faster.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Alavi dormitory,no. 2 ,Mollasadra street,namazi squ,shiraz
City
Shiraz
Province
Fars
Postal code
7193613565
Approval date
2020-10-03, 1399/07/12
Ethics committee reference number
IR.SUMS.MED.REC.1399.388

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
The severity of the symptoms of obsessive -compulsive disorder
Timepoint
The beginning of the study and 2-4-6-8-12 weeks after the start of treatment
Method of measurement
Based on the questionnaire Y-BOCS

Secondary outcomes

empty

Intervention groups

1

Description
Sertraline tablets at a dose of 100-300 mg per day (depending on patient tolerance) with 7.5 to 30 mg of mirtazapine daily for 12 weeks as an intervention group
Category
Treatment - Drugs

2

Description
Sertraline tablets at a dose of 100-300 mg per day (depending on patient tolerance) with placebo for 12 weeks as a control group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
درمانگاه روان پزشکی بیمارستان حافظ
Full name of responsible person
دکتر ارش مولا
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research,shiraz university of medical Scinces
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Grant name
Form the budget of shiraz university of medical sciences
Grant code / Reference number
معاونت پژوهشی دانشگاه علوم پزشکی شیراز
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
Haniyeh baniasadipour
Position
Resident
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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
Information about the main outcome will be shared after the study.
When the data will become available and for how long
6 months after the end of the study
To whom data/document is available
All researchers working in academic and scientific institutions and people working in industry
Under which criteria data/document could be used
Use in the treatment of patients Use in research
From where data/document is obtainable
Shiraz University of Medical Sciences (Vice Chancellor for Research)
What processes are involved for a request to access data/document
Send a request to the research assistant expert, review by the relevant expert.
Comments
Our protocol and data can be published and after completing the study ,we can publish them 6 months later