Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Clinical trial of comparing the effects of Escitalopram with Setraline on the severity of signs and symptoms of patients with obsessive compulsive disorder

Protocol summary

Summary

(1) Goals: In this study we want to compare the effects of Escitalopram with Sertraline on the severity of signs and symptoms of obsessive compulsive disorder (OCD). (2) Design, Setting and Conduct: This is a randomized double blind clinical trial that will be done during six weeks. Participants are OCD patients that will be selected from outpatient and inpatient cases that refer to Shiraz university therapeutic clinics and hospitals. The sample volume includes 70 patients, divided into two separate groups randomly by blocking randomization, group A (intervention group) and group B (control group), 35 patients in each group. Physical exam, clinical diagnosis and drug prescription will be done by psychiatrist, but evaluation of the signs, symptoms and side effects will be done by the assistant. (3) Inclusion Criteria and Exclusion Criteria: Inclusion criteria includes patients with OCD that diagnosed with interview by psychiatrist according to DSM-IV TR; Yale-Brown-obsessive-compulsive scale equal or more than 18; Informed consent of patients. Exclusion criteria includes other psychiatric disorder diagnosis according to axis I and II; Major medical illness like hypertension, diabetes, cardiovascular disease, renal disease and gastrointestinal disease; Pregnancy and lactation; Substance or alcohol abuse; Any intolerable adverse side effects of treatment; Any SSRI usage in past 5 weeks; Patients younger than 18 years and older than 65 years old. (4) Interventions: Intervention group (group A) will receive Escitalopram for 6 weeks. Escitalopram tablets are 10mg tablets. Making all tablets the same series. The initial dose for Escitalopram is 10mg per day and will be increased till patients clinically respond or side effects appear. Maximum dose for Escitalopram is 20mg per day. Control group (group B) will receive Sertraline for 6 weeks. Sertraline tablets are 50mg tablets. Making all tablets the same series. The initial dose for Sertraline is 50mg per day and will be increased till patients clinically response or side effects appear. Maximum dose for Sertraline is 200mg per day. (5) Primary outcome measures: The severity of OCD signs and symptoms is the primary outcome measure in this study. Severity of the OCD signs and symptoms will be evaluated by Yale Brown Obsessive Compulsive Scale (Y-BOCS) at the beginning of the study and at the end of the 6th week of study. To evaluate the clinical response, Clinical Global Impressions Improvement Scale (CGII) will be used at the end of the study, too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020421745N4**
Registration date: **2016-04-20, 1395/02/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-20, 1395/02/01

Registrant information

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Arash Mowla
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Recruitment status

Recruitment complete

Funding source
Vice Chancellor of Research Shiraz University of Medical Sciences

Expected recruitment start date
2016-04-03, 1395/01/15
Expected recruitment end date
2016-09-21, 1395/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of comparing the effects of Escitalopram with Setraline on the severity of signs and symptoms of patients with obsessive compulsive disorder

Public title
Effects of Escitalopram in treatment of patients with obsession
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients with obsessive compulsive disorder (OCD) that diagnosed with interview by psychiatrist according to DSM-IV TR; Yale-Brown-obsessive-compulsive scale equal or more than 18; Informed consent of patients. Exclusion criteria: Other psychiatric disorder diagnosis according to axis I and II; Major medical illness like hypertension, diabetes, cardiovascular disease, renal disease and gastrointestinal disease; Pregnancy and lactation; Substance or alcohol abuse; Any intolerable adverse side effects of treatment; Any SSRI usage in past 5 weeks; Patients younger than 18 years and older than 65 years old.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The type of randomization in this study is blocking randomization. This study is a double blind study; The patients and the assistant that evaluates severity of signs and symptoms and primary outcome measures do not know about the type of the intervention that each patient had received. Just the psychiatrist knows about the name of the drug which is prescribed for each patient.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shiraz University of Medical Science
Street address
Medical school, Zand avenue
City
Shiraz
Postal code
Approval date
2016-01-30, 1394/11/10
Ethics committee reference number
IR.SUMS.MED.REC.1394.67

Health conditions studied

1

Description of health condition studied
obsessive compulsive disorder
ICD-10 code
F42
ICD-10 code description
The essential feature is recurrent obsessional thoughts or compulsive acts. Obsessional thoughts are ideas, images, or impulses that enter the patient's mind again and again in a stereotyped form. They are almost invariably distressing and the patient oft

Primary outcomes

1

Description
Severity of signs and symptoms of the patients with obcessive compulsive disorder
Timepoint
At the beginning of study and at the sixth week of study
Method of measurement
Y-BOCS At the beginning of study and at the sixth week of study and CGI-Improvement test at sixth week of study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (group A) will receive Escitalopram for 6 weeks. Escitalopram tablets are 10mg tablets that are produced by Hakim pharmaceutical company. Making all tablets the same series.The initial dose for Escitalopram is 10mg per day and will be increased till patients clinically response or side effects appear. Maximum dose for Escitalopram is 20mg per day. Physical exam, clinical diagnosis and drug prescription will be done by psychiatrist, but evaluation of the signs and symptoms and side effects will be done by the assistant. Severity of the OCD signs and symptoms will be evaluated by Yale Brown Obsessive Compulsive Scale (Y-BOCS) at the beginning of the study and at the end of the 6th week of study. To evaluate the clinical response Clinical Global Impressions Improvement Scale (CGII) will be used at the end of the study, too. Y-BOCS is a validated questionnaire that is widely used in clinical practice and research to assess the severity and to follow the improvement of clinical features. Y-BOCS consists of 10 items and each item is scored from 0 to 4. The questionnaire includes how much time does the patient spend on obsession, the problems that they have in their life as a result of OCD, how much control does the patient have on the obsessional thoughts and etc. CGI is a quantitative questionnaire, that consists of 2 scales, one for severity and the other for improvement of the disorder. Each scale is scored ranging from 0 to 7. In this study just improvement scale will be used at the end of the study. This test is widely used in the clinic for different anxiety disorders.

Category

Treatment - Drugs

2

Description

Control group (group B) will receive Sertraline for 6 weeks. Sertraline tablets are 50mg tablets that are produced by Sobhandaroo pharmaceutical company. Making all tablets the same series.The initial dose for Sertraline is 50mg per day and will be increased till patients clinically response or side effects appear. Maximum dose for Sertraline is 200mg per day. Physical exam, clinical diagnosis and drug prescription will be done by psychiatrist, but evaluation of the signs and symptoms and side effects will be done by the assistant. Severity of the OCD signs and symptoms will be evaluate by Yale Brown Obsessive Compulsive Scale (Y-BOCS) at the beginning of the study and at the end of the 6th week of study. To evaluate the clinical response Clinical Global Impressions Improvement Scale (CGII) will be used at the end of the study, too. Y-BOCS is a validated questionnaire that is widely used in clinical practice and research to assess the severity and to follow the improvement of clinical features. Y-BOCS consists of 10 items and each item is scored from 0 to 4. The questionnaire includes how much time does the patient spend on obsession, the problems that they have in their life as a result of OCD, how much control does the patient have on the obsessional thoughts and etc. CGI is a quantitative questionnaire, that consists of 2 scales, one for severity and the other for improvement of the disorder. Each item is scored ranging from 0 to 7. In this study just improvement scale will be used at the end of the study. This test is widely used in the clinic for different anxiety disorders.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Arash Mowlaa

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Ebne Sina Hospital

Full name of responsible person

Arash Mowlaa

Street address

City

Shiraz

3

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research Shiraz University of Medical Sciences

Full name of responsible person

Arash Mowla

Street address

Shiraz University of Medical Sciences, Zand Blvd

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of research Shiraz University of Medical Sciences
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
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Full name of responsible person
Farzaneh Modaresi
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Arash mowlaa
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Person responsible for updating data

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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