

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Clinical trial of comparing the effects of Escitalopram with Sertraline 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

###### Name

Arash Mowla

###### Name of organization / entity

Shiraz university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3627 1814

###### Email address

mowlaar@sums.ac.ir

##### 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 obsessive 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

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#### 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

**Name of organization / entity**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Farzaneh Modaresi

**Position**  
psychiatry resident

**Other areas of specialty/work**

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Department of Psychiatry, Hafez Hospital, Chamran Avenue

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## Person responsible for scientific inquiries

### Contact

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**Position**  
Assistant Professor

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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drfarzanehmodaresi84@yahoo.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*