

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the efficacy of adding clonidine to SSRI and treating patients with SSRI alone in patients with treatment-resistant obsessive compulsive disorder

#### Protocol summary

##### Study aim

Determine the efficacy of adding clonidine to the treatment of obesity-resistant obesity disorders

##### Design

Clinical trial with parallel control group, double blind, randomized phase 4 with 30 patients

##### Settings and conduct

Patients with obsessive-compulsive disorder, based on Clinical Neuropsychiatry 2013, who have been treated with a maximum dose of SSRI or clomipramine for at least 12 weeks, with a scoring scale of more than 16 (YBOCS) and clinics Obsessions at the Noor Hospital and the Psychiatric Clinic will add. 30 patients will be enrolled in this study. In this method, patients will be divided into two groups of intervention and placebo in a randomized block. In this study, patients and therapist are unaware of the drug. In the intervention group, clonidine tablets start with a dose of 0.1 mg per night, and 0.2 mg daily are administered to a maximum of 1 mg per day. placebo will be given to control group. In both groups SSRIs or clomipramines will continue with the previous dose and the YBOCS OCD will be completed at the end of the week 4-8 and 12.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria 1-The presence of obsessive-compulsive disorder criteria based on DSM-V-TR 2. Receive at least 12 weeks with a maximum dose of a serotonergic drug (SSRI or clomipramine) 3. moderate or severe symptoms on a scale of obsessive - compulsive Yale-Brown (YBOCS) to score more than 16 r. No initial diagnosis of psychiatric disorders and mood disorder (Bipolar or MDD) Exclusion Criteria: 1- Pregnancy at each stage of the research 2- Cancellation of participation in the study at each stage of the research

##### Intervention groups

Intervention group, patients initially opened a dose of 0.1 mg of clonidine per night, and each week, 0.2 mg is

added to this dose to reach 1 mg / day, and in Control group patients will use placebo.

##### Main outcome variables

Obsessive-Compulsive Scale YBOCS

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110918007582N2**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **prospective**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

##### Registration date

2018-12-01, 1397/09/10

##### Registrant information

##### Name

shahla akuchekian

##### Name of organization / entity

Isfahan university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1222 2127

##### Email address

akuchekian@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-08-23, 1398/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of adding clonidine to SSRI and treating patients with SSRI alone in patients with treatment-resistant obsessive compulsive disorder

**Public title**

Evaluation of Clonidine Therapeutic Effect Added to Usual Treatment in Refractory Obsessive –Compulsive Disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The presence of obsessive-compulsive disorder criteria based on DSM-V-TR Receive at least 12 weeks with a maximum dose of a serotonergic drug (SSRI or Clomipramine) Moderate to severe symptoms based on the obsessive-compulsive- Yerobyll-Brown scale (YBOCS) with a score of more than 16 Obtain informed consent from the patient No initial diagnosis of psychiatric disorders and mood disorder (bipolar or MDD) Absence of drug use or dependence There is no uncontrolled physical illness (such as diabetes, blood pressure, etc.) There is no previous history of Clonidine use Lack of pregnancy and lactation or planning for pregnancy during the study There is no seizure disorder No suicide attempt Not taking beta-blocker Failure to receive synchronous psychological intervention

**Exclusion criteria:**

Cancellation of participation in the study at each stage of the research Pregnancy at each stage of the research

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: 30

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization using a random number table for people with obsessive-compulsive disorder. The random numbers and numbers are extracted by the computer and for allocation concealment unique code will be use.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients do not know about their treatment, and medications are given in asymptomatic packagings to

clinicians not to be aware about the pateint's treatment during the course.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Science

**Street address**

Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673441

**Approval date**

2018-10-08, 1397/07/16

**Ethics committee reference number**

IR.MUI.MED.REC.1397.085

**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**

OCD Scale changes with YBOCS questionnaire

**Timepoint**

Before the intervention and at the end of 4-8-12 weeks

**Method of measurement**

Yale Brown Obsessive-Compulsive Scale (YBOCS)

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Clonidine tablets start with a dose of 0.1 mg once a night, and weekly (based on patient tolerance) 0.2 mg will add to reach a maximum of one mg per day. This dose is based on the administration of clonidine in other psychiatric disorders

### Category

Treatment - Drugs

## 2

### Description

Control group: Will use placebo

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Noor Hospital

##### Full name of responsible person

Dr Shahla Akuchekian

##### Street address

Isfahan Province, Isfahan, Ostandari Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

5138663134

##### Phone

+98 31 3222 2127

##### Email

akuchekian@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Shahryar Moazeni

##### Street address

Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

5138663134

##### Phone

+98 31 3222 2127

##### Email

akuchekian@med.mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Shahla Akuchekian

##### Position

Psychaitric Assistant Profesor

##### Latest degree

Specialist

##### Other areas of specialty/work

Psychiatrics

##### Street address

Isfahan university

##### City

Isfahan

##### Province

Isfahan

##### Postal code

5138663134

##### Phone

+98 31 1222 2127

##### Fax

+98 31 2222 2145

##### Email

akuchekian@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shahla Akuchekian

##### Position

Psychaitric Assistant Profesor

##### Latest degree

Specialist

##### Other areas of specialty/work

Psychiatrics

##### Street address

Isfahan university

**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
5138663134  
**Phone**  
+98 31 1222 2127  
**Fax**  
+98 31 2222 2145  
**Email**  
akuchekian@med.mui.ac.ir

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Shahla Akuchekian  
**Position**  
Psychaitric Assistant Profesor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Isfahan university  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
5138663134  
**Phone**  
+98 31 1222 2127  
**Fax**

+98 31 2222 2145

**Email**  
akuchekian@med.mui.ac.ir

## 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

All data will be available.

### When the data will become available and for how long

Access will begin immediately after the article is publish.

### To whom data/document is available

Data will be available to all people.

### Under which criteria data/document could be used

All the necessary analyzes can be done and there are no specific conditions for access.

### From where data/document is obtainable

Send applicant to Dr. Akuchekian, email her at akuchekian@med.mui.ac.ir

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

In the shortest time it will be available to the applicant.

### Comments