Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ۴. 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
Iintervention 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 Sciense
Street address
Isfahan
City
Isfahan
Province
Isfehan
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
Isfehan

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
Isfehan

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
Isfehan

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

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Isfahan university

City
Isfahan
Province
Isfehan
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
Isfehan
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