Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Reboxetine combination therapy with Fluoxetine in the treatment of moderate to severe obsessive-compulsive disorder: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim
Reboxetine combination therapy with Fluoxetine in the treatment of moderate to severe obsessive-compulsive disorder

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
The study will be performed on patients with moderate to severe obsessive-compulsive disorder attending Roozbeh and Navab Safavi Hospitals

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 to 60 years - Diagnosis of moderate to severe OCD based on DSM-5 - Score of >21 in Yale–Brown obsessive-compulsive scale (Y-BOCS). Exclusion criteria: Receiving any treatment up to 6 weeks before the start of the trial - Presence of another psychiatric disorder

Intervention groups
Patients with moderate to severe obsessive-compulsive disorder (based on DSM-5 diagnostic criteria) are included in the study and divided into two control (25 participants) and intervention (25 participants) groups. Patients in the intervention group receive Reboxetine and Fluoxetine for 10 weeks, and patients in the control group receive Fluoxetine and placebo for 10 weeks. Patients are evaluated at weeks 0, 5, and 10 by Yale-Brown obsessive-compulsive scale (Y-BOCS).

Main outcome variables
Severity of obsessive-compulsive disorder (OCD)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N129**
Registration date: **2020-05-20, 1399/02/31**
Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**
Update count: **0**

Registration date
2020-05-20, 1399/02/31

Registrant information

Name
Shahin Akhondzadeh

Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 5541 2222

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-10, 1399/04/20

Expected recruitment end date
2022-07-11, 1401/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Reboxetine combination therapy with Fluoxetine in the treatment of moderate to severe obsessive-compulsive

disorder: A randomized double blind and placebo controlled clinical trial

Public title
Reboxetine combination Therapy with Fluoxetine in the treatment of obsessive-compulsive disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 60 years Diagnosis of moderate to severe OCD based on DSM-5 Score of >21 in Yale–Brown obsessive-compulsive scale (Y-BOCS)
Exclusion criteria:
Receiving any treatment up to 6 weeks before the start of the trial Presence of another psychiatric disorder
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups)
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.
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Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-12-22, 1398/10/01
Ethics committee reference number
IR.TUMS.VCR.REC.1398.1017

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
Severity of OCD symptoms
Timepoint
Baseline and weeks 5 and 10
Method of measurement
By Yale–Brown obsessive-compulsive scale (Y-BOCS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Fluoxetine tablet (Abidi co.) 80 mg once per day + Reboxetine (Pfizer co.) tablet 10 mg BID, for 10 weeks
Category
Treatment - Drugs

2

Description
Control group: Fluoxetine tablet (Abidi co.) 80 mg once per day + Placebo tablet (BID), for 10 weeks
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh hospital
Full name of responsible person
Prof. Mohammad Reza Mohammadi
Street address
Roozbeh Hospital, South Kargar Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
Latest degree
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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
No - There is not a plan to make this available
Title and more details about the data/document
The data will be distributed through final report
When the data will become available and for how long
5 years from 2021 to 2026
To whom data/document is available
academic researchers
Under which criteria data/document could be used
users should cite the resource of data
From where data/document is obtainable
Prof Shahin Akhondzadeh
What processes are involved for a request to access data/document
by E mail
Comments