Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Efficacy of Granisetron as Adjunctive Therapy in Obsessive Compulsive Disorder A Double-blind, Placebo-controlled, Randomized Trial

Protocol summary

Study aim
Comparison of treatment effect on OCD patients with Granisetron plus Sertraline comparing with Placebo and Setraline

Design
Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To do study with concealment, table of block will be used by one of researches, other than interviewer and who will assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who will assess patients in follow-up visits will be unaware of each number belongs to which groups.

Settings and conduct
Outpatients OCD patients who will come to psychiatric outpatients clinics of Iran University of Medical Sciences will be recruited.

Participants/Inclusion and exclusion criteria
Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 years old and sign consent form. they should not be treated by any psychiatric interventions for 6 weeks ago. If they show any other mental important conditions or suicidal thoughts, neurological deficits, exclude from study. They will evaluate for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.

Intervention groups
Granisetron plus Setraline and Placebo plus Sertraline

Main outcome variables
Severity of obsessive-compulsive disorder

General information

Reason for update

Acronym
OCD

IRCT registration information
IRCT registration number: **IRCT20170123032145N3**
Registration date: **2019-03-27, 1398/01/07**
Registration timing: **prospective**

Last update: **2019-03-27, 1398/01/07**
Update count: **0**

Registration date
2019-03-27, 1398/01/07

Registrant information

Name
Mohammadreza Shalbafan

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 6655 1665

Email address
shalbafan.mr@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-06, 1398/01/17

Expected recruitment end date
2020-03-18, 1398/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Efficacy of Granisetron as Adjunctive Therapy in Obsessive Compulsive Disorder A Double-blind, Placebo-controlled, Randomized Trial

Public title
Granisetron for treatment of Obsessive-Compulsive Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 years old Sign consent form
Exclusion criteria:
They should not be treated by any psychiatric interventions for 6 weeks ago. If they show any other mental important conditions or suicidal thoughts, neurological deficits, exclude from study. They will be evaluated for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks.
Blinding (investigator's opinion)
Triple blinded
Blinding description
To do study with concealment, table of block will be used by one of researches, other than interviewer and who will assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who will assess patients in follow-up visits will be unaware of each number belongs to which groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2019-03-14, 1397/12/23
Ethics committee reference number
IR.IUMS.FMD.REC.1397.198

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 obsessive-compulsive disorder
Timepoint
Weeks: 0, 4, 8 and 10
Method of measurement
Yale-Brown Obsessive Compulsive Scale(YBOCS)

Secondary outcomes

1

Description
Side effects
Timepoint
Weeks: 1, 4, 8 and 10
Method of measurement
Checklist

Intervention groups

1

Description
Intervention group: Sertraline(Tab) up to 200 mg/day plus Granisetron(Tab) 1mg twice per day for 10 weeks
Category
Treatment - Drugs

2

Description
Control group: Sertraline(Tab) up to 200 mg/day plus placebo(Tab) twice per day for 10 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran Psychiatric Hospital
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Tehran-Karaj Highway 7 km
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1398913151
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Shalbafan.mr@iums.ac.ir
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2

Recruitment center
Name of recruitment center
Tehran Psychiatric Institute
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr Kazem Malakouti
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Phone
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Email
mhrc@iums.ac.ir
Web page address
http://mhrc.iums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Shalbafan
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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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
Not applicable
Title and more details about the data/document
Data about main outcome of study will be published
When the data will become available and for how long
2021
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
For scientific goals
From where data/document is obtainable
shalbafan.mr@iums.ac.ir Dr Mohammadreza Shalbafan
What processes are involved for a request to access data/document
Sending an E-mail and reason for request
Comments