

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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)

Phone

+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

City

Tehran

Province

Tehran

Postal code

1398913151

Phone

+98 21 4450 3395

Email

Shalbafan.mr@iums.ac.ir

Web page address

<http://iph.iums.ac.ir/>

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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shalbafa.mr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Kazem Malakouti

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

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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**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

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Position

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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