Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of Ondansetron and Granisetron Effectiveness in the Treatment of Obsessive-Compulsive Disorder with Inadequate Response to Selective Serotonin Reuptake Inhibitors

Protocol summary

Study aim
Comparison of Ondansetron and Granisetron Effectiveness in the Treatment of Obsessive-Compulsive Disorder

Design
A randomized, double-blind, placebo-controlled, phase III clinical trial was conducted on 104 patients with obsessive-compulsive disorder. Patients were divided into three groups that either received 18 weeks of ondansetron (intervention group 1), granisetron (intervention group 1) or placebo (control group) in addition to baseline treatment with selective serotonin reuptake inhibitors. Randomization of patients was done using the random permuted block method (allocation ratio 1:1, blocks of four).

Settings and conduct
Ondonestrone and granisetron are inhibitors of serotonin receptors. This clinical trial is conducted among outpatients of the psychiatric department of Amir Kabir Hospital, Arak. Patients were enrolled in the intervention group 1 (Ondosanone), intervention group 2 (granisetron) and control (placebo).The patients, the psychiatrist who referred the patients, the general practitioner who evaluated the patients and prescribed the medication were all blind to allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Resistant or inadequacy of Serotonin reuptake inhibitor (SRIs) treatment response. Exclusion criteria: other significant psychiatric disorders Recent receiving antipsychotics in the treatment of obsessive-compulsive disorder, having significant cardiovascular, hepatic, renal or pulmonary diseases

Intervention groups
Intervention group 1: Oral ondansetron tablet 2 mg in twice daily (4 mg daily) for 18 weeks. Intervention group 2: Oral granisetron tablet 1 mg in twice daily (2 mg daily) for 18 weeks. Control group:Oral placebo tablets were administered daily for 18 weeks.

Main outcome variables
Changes from baseline Yale-Brown Obsessive Compulsive Scale (YBOCS) total, Obsession and Compulsion subscale score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130726014170N2**
Registration date: **2018-04-23, 1397/02/03**
Registration timing: **retrospective**

Last update: **2018-04-23, 1397/02/03**
Update count: **0**

Registration date
2018-04-23, 1397/02/03

Registrant information

Name
Mojtaba Sharafkhah

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 911 918 0298

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sharafkhah@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2014-08-20, 1393/05/29

Expected recruitment end date

2016-09-19, 1395/06/29

Actual recruitment start date

2014-12-21, 1393/09/30

Actual recruitment end date

2017-09-20, 1396/06/29

Trial completion date

empty

Scientific title

Comparison of Ondansetron and Granisetron Effectiveness in the Treatment of Obsessive-Compulsive Disorder with Inadequate Response to Selective Serotonin Reuptake Inhibitors

Public title

The Effectiveness of Ondonestrone and Granisetron in the Treatment of Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of OCD established by clinical interview (using The Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders IV (DSM-IV) Axis I Disorders) Resistant or inadequacy of Serotonin reuptake inhibitor (SRIs) treatment response

Exclusion criteria:

Diagnosis of schizophrenia, schizoaffective disorder, organic mental disorder, bipolar disorder, substance dependence or abuse, and other comorbid DSM-IV Axis I disorders History of seizure, suicidal ideation, and significant head trauma Recent receiving antipsychotics in the treatment of obsessive-compulsive disorder Intelligence quotient less than 70 history of treatment resistance pregnancy and/or lactation Having significant cardiovascular, hepatic, renal or pulmonary diseases

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **104**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients is based on the use of the random permuted block method (allocation ratio 1:1, blocks of four). Treatment allocation is concealed from the participants and physicians rated the patients using sequentially numbered, opaque and sealed envelopes. Randomizations and ratings of the patients are performed by separate individuals.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, the psychologist who referred the patients, the general physician and psychologist who evaluated the patients and prescribed the medication and the statistician were all blind to allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Shahid Shiroodi St., Aalam Al-Hoda St., Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2014-08-05, 1393/05/14

Ethics committee reference number

93-166-5

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

changes from baseline Yale-Brown Obsessive Compulsive Scale (YBOCS) total, Obsession and Compulsion subscale score

Timepoint

Every two weeks for 18 weeks

Method of measurement

Yale-Brown Obsessive Compulsive Scale (YBOCS)

Secondary outcomes

1

Description
Partial treatment response
Timepoint
Every two weeks for 18 weeks
Method of measurement
Yale-Brown Obsessive Compulsive Scale (YBOCS)

Intervention groups

1

Description
Intervention group: Continued treatment with serotonin reuptake inhibitor along with oral ondansetron tablet 2 mg in twice daily (4 mg daily) for 18 weeks. Ondansetron was provided by Jaber Ibn Hayyan pharmaceutical company,Tehran, Iran.
Category
Treatment - Drugs

2

Description
Intervention group: Continued treatment with serotonin reuptake inhibitor along with oral granisetron tablet 1 mg in twice daily (2 mg daily) for 18 weeks. Granisetron was provided by Jaber Ibn Hayyan pharmaceutical company,Tehran, Iran.
Category
Treatment - Drugs

3

Description
Control group: Oral placebo tablets were administered daily for 18 weeks. The placebo were provided by Jaber Ibn Hayyan pharmaceutical company, Iran.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir hospital
Full name of responsible person
Mohsen Rahimi
Street address
Shahid Shiroodi Street, Amir Kabir Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available