

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

Ondansetron 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 (Ondansetron), 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)

Phone

+98 911 918 0298

Email address

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

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Email

info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Akram Moslemi

Street address

Basij Square, Sardasht, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3639

Email

Rsearch@arakmu.ac.ir

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

Full name of responsible person

Mojtaba Sharafkhah

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

Street address

No. 4, Shaghayegh 24 Ave, Kochaksara street

City

قائم شهر

Province

Mazandaran

Postal code

4763658894

Phone

+98 11 4224 8158

Email

dr.sharafkhah@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mojtaba Sharafkhah

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

Street address

No. 4, Shaghayegh 24 Ave, Kochaksara street

City

Ghaemshahr

Province

Mazandaran

Postal code

4763658894

Phone

+98 11 4224 8158

Email

dr.sharafkhah@yahoo.com

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

Arak University of Medical Sciences

Full name of responsible person

Mojtaba Sharafkhah

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

Street address

No. 4, Shaghayegh 24 Ave, Kochaksara street

City

Ghaemshahr

Province

Mazandaran

Postal code

4763658894

Phone

+98 11 4224 8158

Email

dr.sharafkhah@yahoo.com

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