

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Ondansetron augmentation therapeutic effectiveness in Obsessive Compulsive disorder patients resistant to treatment by selective serotonin reuptake inhibitor: Double-blind randomized clinical trial with placebo control

Protocol summary

Study aim

Evaluation of the Therapeutic Effect of Adding Ondansetron in Patients with Treatment-Resistant Obsessive-Compulsive Disorder Under Serotonin Reuptake Inhibitor Therapy

Design

Phase 3 randomized, double-blind, parallel-group, controlled clinical trial on 40 patients. Block randomization will be performed, with an allocation ratio of 1:1

Settings and conduct

Background: At Rasht, Psychiatry Outpatient Clinic; investigating the effect of ondansetron in treatment-resistant Obsessive Compulsive Disorder ,Method: Double-blind, randomized, placebo-controlled.Sample:40 patients divided into two groups of 20(ondansetron vs. placebo).Assessment:Day 0, Week 8, and Week 12, Blinding:Patients, physicians, and outcome assessors are unaware of the intervention

Participants/Inclusion and exclusion criteria

Inclusion: Diagnosis of obsessive-compulsive disorder based on the Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition ,Age range: 18 to 50 years, Total score of the Yale-Brown Obsessive Compulsive Scale above 16, Ventricular electrical interval(QT) less than 420 milliseconds on ECG prior to the start of the study, No history of prolonged ventricular electrical interval syndrome in the patient or their family Exclusion:Active psychosis, Serious medical conditions, Cardiac issues/family history, Substance use, Intellectual disability, Pregnancy/lactation, Concurrent psychotherapy

Intervention groups

Intervention Group:4 mg ondansetron,daily manufactured by Sobhan Darou Company for 12 weeks with an serotonin reuptake inhibitor; Control Group:

placeb ,daily manufactured by Sobhan Darou Company for 12 weeks with an serotonin reuptake inhibitor

Main outcome variables

Severity of Obsessive Compulsive Disorder symptom based on the Yale-Brown Obsessive Compulsive Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250523065856N1**

Registration date: **2025-12-15, 1404/09/24**

Registration timing: **retrospective**

Last update: **2025-12-15, 1404/09/24**

Update count: **0**

Registration date

2025-12-15, 1404/09/24

Registrant information

Name

Nadia Vakili sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3211 4085

Email address

n.vakilisadeghi@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-01, 1404/03/11

Expected recruitment end date

2025-08-02, 1404/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Ondansetron augmentation therapeutic effectiveness in Obsessive Compulsive disorder patients resistant to treatment by selective serotonin reuptake inhibitor: Double-blind randomized clinical trial with placebo control

Public title

Evaluation of Ondansetron effect in treatment resistant Obsessive Compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of obsessive-compulsive disorder based on the Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition Age range: 18 to 50 years Total score of the Yale-Brown Obsessive Compulsive Scale above 16 Ventricular electrical(QT)interval less than 420 milliseconds on ECG prior to the start of the study No history of prolonged ventricular electrical interval syndrome in the patient or their family

Exclusion criteria:

Active phase of psychotic disorders such as schizophrenia and major depression Concurrent serious medical illness including hepatic, renal, and electrolyte problems (any abnormal paraclinical findings in serum urea,creatinin,liver function test,blood chemistry) Cardiac problems in the individual (including structural, conduction, or vascular disorders) or a family history of cardiac conduction disorders Structural brain disease Alcohol and substance use Intellectual disability Pregnancy and breastfeeding period Undergoing any form of psychotherapy at present

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

1. Randomization method: Block randomization with an allocation ratio of 1:1 between two groups, with a block

size of 4. 2. Unit of randomization: Individual 3. Stratification: Not used. 4. Randomization tool: The random sequence was generated based on the method described in the article with the digital object identifier (DOI) "10.22034/PJMS.2022.700469". The tool used was the Random Allocation Software. Allocation was performed using pre-generated, numbered codes enclosed in sealed opaque envelopes. 5. Sequence generation: The random sequence was generated and maintained by a researcher not involved in data assessment and analysis. 6. Allocation concealment: To maintain allocation concealment, sequentially numbered, sealed, and coded envelopes were used. Patient evaluation and allocation were performed by separate individuals, and treatment information was kept blinded to both the clinical assessor and the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

1. Participants (Patients): All participants are unaware of the type of intervention (drug or placebo). The drug and placebo have been prepared to be identical in appearance, color, and packaging. Patients are only aware of their participation in a treatment study but do not know the type of intervention they are receiving. 2. Healthcare Personnel (Faculty Responsible for Patient Visits): Two faculty members responsible for the initial visits and follow-up of patients are unaware of the intervention allocation (drug or placebo) and operate in a blinded manner. 3. Principal Investigator: The principal investigator assigns patients to two groups based on a randomization table at the beginning of the study and is the only person aware of the intervention allocation. They are not blinded. 4. Data Collectors: Study data is collected by the principal investigator. Since they are aware of the intervention type, this phase is conducted in a non-blinded manner. However, structured forms and pre-defined checklists are used to minimize bias. 5. Outcome Assessors: Faculty members responsible for evaluating the response to treatment are unaware of the allocation of patients to either the drug or placebo group. Therefore, outcome assessment is conducted in a blinded manner. 6. Data Safety and Monitoring Committee (DSMC): An independent committee for data safety monitoring has not been established for this study. Safety monitoring and potential adverse events are overseen by the principal investigator, with decisions made in consultation with supervising faculty when necessary. 7. Final Article Author: The final article author is the principal investigator, who is aware of the intervention allocation. However, the data is provided to a statistician in a coded format without reference to the intervention type, ensuring statistical analysis is conducted without knowledge of treatment allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, Guilan University of Medical Sciences

Street address

University Research and Technology Vice-Chancellor, in front of 17 Shahrivar Hospital, Shahid Siyadati St, Namjo St, Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2025-05-07, 1404/02/17

Ethics committee reference number

IR.GUMS.REC.1404.062

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

Obsessive Compulsive Disorder symptom severity based on the Yale-Brown Obsessive Compulsive Scale

Timepoint

Before the intervention, 8 weeks and 12 weeks after the start of the intervention

Method of measurement

Yale-Brown Obsessive Compulsive Scale

Secondary outcomes

1

Description

Response to treatment (more than 35% reduction in Yale-Brown Obsessive Compulsive Scale)

Timepoint

Before the intervention, 8 weeks and 12 weeks after the start of the intervention

Method of measurement

Yale-Brown Obsessive Compulsive Scale

2

Description

Safety of ondansetron

Timepoint

Before the intervention, 8 weeks and 12 weeks after the start of the intervention

Method of measurement

Clinical interview

3

Description

Tolerability of ondansetron (QT interval changes)

Timepoint

Before the intervention, 8 weeks and 12 weeks after the start of the intervention

Method of measurement

Electrocardiography

Intervention groups

1

Description

Intervention group: The intervention group is a group of 20 people who will receive ondansetron by a medical assistant. This medication belongs to the class of serotonin 5-HT₃ receptor antagonists, and its chemical nature is recognized as an anti-emetic agent. The pharmaceutical form of the drug is an oral tablet, manufactured by Sobhan Darou Company. In the intervention group, participants will take one 4-mg tablet of ondansetron daily, administered orally. The dosage remains fixed and does not change throughout the study. The total duration of drug administration is 12 weeks. This intervention is a Drug Intervention and consists of the daily use of an ondansetron tablet with a defined dose, defined route of administration, and defined duration.

Category

Treatment - Drugs

2

Description

Control group: The control group is a group of 20 people who will take placebo pills without any active pharmaceutical ingredient. The placebo tablet is designed to resemble the ondansetron tablet in appearance, size, and route of administration. The pharmaceutical form is an oral tablet, manufactured by Sobhan Darou Company. Participants in this group will take one placebo tablet daily, administered orally. The dosage and frequency of administration remain fixed and do not change during the study. The duration of placebo use is 12 weeks. This intervention is a Drug Intervention (placebo) and consists of the daily use of a tablet without an active ingredient, with a defined dose, defined route of administration, and defined duration.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Outpatient Clinic for Obsessive-Compulsive Disorder Treatment

Full name of responsible person

Seyed Mohammad Rasool Khalkhali Sharifi

Street address

Shafa Hospital, 15 Khordad Street, Imam Boulevard, Rasht, Gilan, Iran

City

Rasht

Province

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Phone

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Rasoolkhalkhalimd@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Ramyar Farzan

Street address

University Research and Technology Vice-Chancellor, in front of 17 Shahrivar Hospital, Shahid Siyadati St, Namjo St, Rasht

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41446-66949

Phone

+98 13 3333 5821

Email

research@gums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Nadia Vakili Sadeghi

Position

Psychiatrist

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

No. 67, Unit 7, Next to Victory Clothing, Before Somayeh Intersection, West Deylaman Blvd, Golsar, Rasht, Gilan, Iran

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Phone

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Email

n.vakilisadeghi@bpums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Nadia Vakili Sadeghi

Position

Psychiatry

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Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Title of Documents and Study Data: "Investigating the Effect of Ondansetron in Treatment-Resistant OCD: A Phase 3 Clinical Trial" Data Details "Type of Data:Includes primary outcome measures (OCD symptom severity, response to treatment, safety, and tolerability of the drug)" "Data Accessibility: Only anonymized data related to primary outcomes will be available for sharing" "Limitations:Individual participant data will not be disclosed to ensure confidentiality"

When the data will become available and for how long

Data Access Timeline: "Start Date:6 months after the

publication of study results" "Access Duration:Unlimited for anonymized primary outcome data"

"Limitations:Individual participant data will not be shared"

To whom data/document is available

Authorized Individuals for Data Access: "Academic and scientific researchers affiliated with reputable research institutes and universities" "Industry professionals in pharmaceutical and healthcare sectors related to clinical research" "Regulatory and medical policy organizations for study result evaluation" Restrictions: "Data will be shared only in anonymized form, and requests must be submitted through official institutions with Ethics Committee approval"

Under which criteria data/document could be used

Conditions and Purpose of Data Usage: "Research Purposes: Anonymized data may only be used for scientific studies and statistical analyses related to Obsessive-Compulsive Disorder (OCD)" "Permitted Analyses: Researchers are allowed to perform statistical analyses, clinical modeling, and meta-analyses on the provided data." "Usage Restrictions:Data must not be used for commercial, promotional, or non-scientific purposes." "Regulatory Oversight:Data usage must comply with Ethics Committee approval and confidentiality standards" "Request Submission Requirements: Researchers must submit a formal request through academic or research institutions and sign a data usage agreement"

From where data/document is obtainable

Guidelines for Requesting Data and Documents: "Priority 1:Official request through the Ethics Committee in Research, Guilan University of Medical Sciences Address:Guilan, Rasht, Guilan University of Medical Sciences, Ethics Committee in Research Email: ethics@gums.ac.ir " " Priority 2:Contact the Study Director or Principal Investigator" "Applicants must submit a formal written request detailing the purpose of data usage and obtain approval from the Ethics Committee."

What processes are involved for a request to access data/document

Process for Requesting and Receiving Data: 1.Submitting an Official Request:The applicant must send a formal written request to the **Ethics Committee at Guilan University of Medical Sciences including the purpose of data usage the type of data required, and their credentials. 2.Review by the Ethics Committee:The request is evaluated for approval or rejection, a process that typically takes 2 to 4 weeks 3.Signing the Data Usage Agreement:If approved, the applicant must sign a confidentiality and data usage agreement before accessing the data. 4.Receiving the Data:Once finalized, anonymized data is shared via email or the research data platform within 1 to 2 weeks Total estimated duration:The process of data access typically takes 4 to 6 weeks depending on review speed.

Comments