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)

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+98 13 3211 4085

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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
Electerocardiography

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

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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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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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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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Nadia Vakili Sadeghi

Position
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Email
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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