Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the Effect of Agomelatine as an Adjunctive Treatment in Obsessive-Compulsive Disorder: A Double-Blind Randomized Controlled Drug Trial

Protocol summary

Study aim
To evaluate the efficacy and safety of agomelatine as an adjunctive treatment in patients with obsessive-compulsive disorder

Design
A double-blind randomized placebo-controlled clinical trial with a parallel-group design will be conducted on 70 patients. Participants will be allocated in a 1:1 ratio to two groups using block randomization and sequentially numbered opaque sealed envelopes

Settings and conduct
After informed consent, 70 patients with obsessive-compulsive disorder based on DSM-5 criteria and a Yale-Brown Obsessive-Compulsive Scale(Y-BOCS) above 18 will be enrolled from Ostad Moharreri clinic/hospital and randomly assigned to two 35-patient intervention and control groups. The trial is double blind; participants, the outcome assessor, and the data analyst will be unaware of allocation. Treatment will follow the intervention descriptions for 16 weeks. Y-BOCS will be assessed at baseline and weeks 4, 8, and 16; adverse effects at weeks 4, 8, and 16; and liver function tests at baseline and the same follow-up weeks.

Participants/Inclusion and exclusion criteria
Adults aged 18-60 with DSM-5 OCD and Yale-Brown Obsessive-Compulsive Scale equal to or more than 18 will be included. Key exclusions are serious medical/neurological or psychiatric comorbidity, substance abuse, pregnancy/breastfeeding, intellectual disability, contraindication/allergy to study drugs, prior full escitalopram treatment, treatment-resistant OCD, recent psychotropic use, concurrent psychotherapy/study, and liver disease or elevated liver enzymes

Intervention groups
Intervention group: escitalopram plus agomelatine 25 mg. Control group: escitalopram plus placebo. In both groups, escitalopram starts at 5 mg and may be increased weekly up to 30 mg. Treatment lasts 16 weeks.

Main outcome variables
Change in Y-BOCS score; adverse drug effects; liver enzymes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260426069173N1**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**

Registration date
2026-06-20, 1405/03/30

Registrant information

Name
Arian Davatgarzade
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3235 1536
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ariandav61@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-30, 1405/02/10

Expected recruitment end date

2026-09-01, 1405/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Agomelatine as an Adjunctive Treatment in Obsessive-Compulsive Disorder: A Double-Blind Randomized Controlled Drug Trial

Public title

Investigating the Effect of Agomelatine in Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 60 years Diagnosis of obsessive-compulsive disorder based on DSM-5 criteria Y-BOCS score equal to or greater than 18 Written informed consent to participate in the study Ability to attend follow-up visits and complete study questionnaires

Exclusion criteria:

Presence of a life-threatening medical condition or neurological disorder Presence of comorbid psychiatric disorder History of substance abuse Pregnancy or breastfeeding Intellectual disability History of severe hypersensitivity or contraindication to agomelatine or escitalopram History of complete treatment with escitalopram History of surgical treatment for obsessive-compulsive disorder Treatment-resistant obsessive-compulsive disorder Use of psychotropic medications during the 6 weeks before study entry Concurrent participation in other studies or psychotherapy during the study Hepatic failure or elevated liver enzymes

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The unit of randomization is the individual participant. Eligible participants will be randomly allocated in a 1:1 ratio to the intervention or control group after obtaining informed consent and definite enrollment in the study. Block randomization will be used, and no stratified randomization will be applied. The random allocation sequence will be generated by the principal investigator using computer-generated random numbers in SPSS. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes. The envelopes will be used according to the order of participant enrollment, and each envelope will be opened only after the patient is definitely enrolled in the study. Before opening the envelope, the allocation sequence will not be accessible to the participant, the outcome assessor, or the main study collaborator.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted as a double-blind trial. Participants and outcome assessors will be unaware of group allocation and the type of intervention, agomelatine or placebo. The active drug and placebo will be identical in appearance, color, and packaging. The data analyst will also remain blinded to group allocation until the analysis is completed. The principal investigator will be aware of liver function test results for safety monitoring

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Km 13, Shiraz-Isfahan Highway, Opposite Niayesh Township, Ostad Moharreri Psychiatric Hospital

City

Shiraz

Province

Fars

Postal code

7144113331

Approval date

2026-02-21, 1404/12/02

Ethics committee reference number

IR.SUMS.MED.REC.1404.648

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
Change in severity of obsessive-compulsive symptoms based on the Y-BOCS score
Timepoint
The test score will be measured at baseline before starting the intervention, and then at the end of weeks 4, 8, and 16 after starting the therapeutic intervention with escitalopram and agomelatine
Method of measurement
Symptom severity will be measured using the Yale-Brown Obsessive Compulsive Scale. This scale includes 10 items, each scored from 0 to 4. Higher scores indicate greater symptom severity

Secondary outcomes

1

Description
Occurrence of adverse drug effects including headache, dizziness, drowsiness, gastrointestinal adverse effects, and skin adverse effects
Timepoint
Adverse drug effects including headache, dizziness, drowsiness, gastrointestinal adverse effects, and skin adverse effects will be assessed at the end of weeks 4, 8, and 16 after starting the therapeutic intervention
Method of measurement
Adverse drug effects including headache, dizziness, drowsiness, gastrointestinal adverse effects, and skin adverse effects will be recorded using an adverse drug effect questionnaire

2

Description
Change or elevation in liver enzymes
Timepoint
Liver enzymes will be measured at baseline before starting the intervention and then at the end of weeks 4, 8, and 16 after starting the therapeutic intervention
Method of measurement
Liver enzymes will be measured by blood tests and liver function tests

Intervention groups

1

Description
Intervention group: Intervention group: Patients will receive escitalopram starting at 5 mg daily, which may be increased by 5 mg weekly if needed up to a maximum of 30 mg daily. In addition, they will receive agomelatine 25 mg daily for 16 weeks. Both drugs will be supplied by Tadbirkala Company.
Category
Treatment - Drugs

2

Description
Control group: Control group: Patients will receive escitalopram starting at 5 mg daily, which may be increased by 5 mg weekly if needed up to a maximum of 30 mg daily. In addition, they will receive a placebo identical to agomelatine for 16 weeks. Both drugs will be supplied by Tadbirkala Company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ostad Moharreri Psychiatric Hospital
Full name of responsible person
Leila Razeghian Jahromi
Street address
Km 13, Shiraz-Isfahan Highway, Opposite Niayesh Township, Ostad Moharreri Psychiatric Hospital
City
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Fars
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7144113331
Phone
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Email
leilarazeghian1366@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Street address
Km 13, Shiraz-Isfahan Highway, Opposite Niayesh Township, Ostad Moharreri Psychiatric Hospital
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Leila Razeghian Jahromi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Leila Razeghian Jahromi
Position
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Latest degree
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Other areas of specialty/work
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Postal code
71441-13331
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leilarazeghian1366@gmail.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
Individual participant data will not be publicly shared due to the confidentiality of mental health information and the possibility of indirect identification of participants. Study results will be published only in aggregate form without identifiable information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

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

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Comments
