

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

Email address

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

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+98 71 3627 7501

Email

leilarazeghian1366@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

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

Street addressKm 13, Shiraz-Isfahan Highway, Opposite Niayesh
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Person responsible for scientific 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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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

Associate professor

Latest degree

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Other areas of specialty/work

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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

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

Comments
