Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Agomelatine as Adjunctive Therapy in Obsessive Compulsive Disorder A Double-blind,Placebo-controlled,Randomized Trial

Protocol summary

Study aim
Comparison of treatment effect of Agomelatine plus Sertraline with Placebo and Setraline on OCD patients

Design
Two arm parallel group randomized trial with blinded postoperative care and outcome assessment. Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which groups.

Settings and conduct
OCD outpatients who come to psychiatric clinics of Iran University of Medical Sciences will be recruited.

Participants/Inclusion and exclusion criteria
Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 year old and sign consent form. They should not be treated by any psychiatric interventions for last 6 weeks. If they show any other important mental condition or suicidal thought, neurological deficit, will exclude from study. They will be evaluated for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.

Intervention groups
Agomelatine plus Setraline and Placebo plus Sertraline

Main outcome variables
Severity of obsessive-compulsive disorder

General information

Reason for update

Acronym
OCD

IRCT registration information
IRCT registration number: **IRCT20170123032145N5**
Registration date: **2020-07-14, 1399/04/24**
Registration timing: **prospective**

Last update: **2020-07-14, 1399/04/24**
Update count: **0**

Registration date
2020-07-14, 1399/04/24

Registrant information

Name
Mohammadreza Shalbafan

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6655 1665

Email address
shalbafan.mr@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Agomelatine as Adjunctive Therapy in Obsessive Compulsive Disorder A Double-blind,Placebo-

controlled,Randomized Trial

Public title
Agomelatine for treatment of Obsessive-Compulsive Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who meet DSM-5 criterion for OCD Achieve more than 21 for Yale-Brown Obsessive Compulsive Scale Age: 18-65 year old Sign consent form
Exclusion criteria:
They should not be treated by any psychiatric intervention for last 6 weeks. If they show any other important mental condition or suicidal thought, neurological deficit, will exclude from study. They will be evaluated for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks
Blinding (investigator's opinion)
Triple blinded
Blinding description
To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who evaluates patients in follow-up visits will be unaware if each number belongs to which groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2020-04-16, 1399/01/28
Ethics committee reference number
IR.IUMS.REC.1399.101

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
Severity of obsessive-compulsive disorder
Timepoint
Weeks: 0, 4, 8 and 12
Method of measurement
Yale-Brown Obsessive Compulsive Scale(YBOCS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sertraline(Tab) up to 200 mg/day plus Agomelatine (Tab) 25 mg daily for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Sertraline(Tab) up to 200 mg/day plus

placebo(Tab) daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Psychiatric Hospital

Full name of responsible person

Dr Mohammadreza Shalbafan

Street address

Tehran-Karaj Highway 7 km

City

Tehran

Province

Tehran

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1398913151

Phone

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Email

Shalbafan.mr@iums.ac.ir

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2

Recruitment center

Name of recruitment center

Tehran Psychiatric Institute

Full name of responsible person

Dr Mohammadreza Shalbafan

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Abbas Motavalian

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Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

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Grant name

High quality articles grant

Grant code / Reference number

98-4-75-16914

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Shalbafan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Assistant Professor

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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data about main outcome of study will be published

When the data will become available and for how long
2024

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
For scientific goals

From where data/document is obtainable
shalbafan.mr@iums.ac.ir Dr Mohammadreza Shalbafan

What processes are involved for a request to access data/document
Sending an E-mail and reason of request

Comments