

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

**Postal code**

1398913151

**Phone**

+98 21 4450 3395

**Email**

Shalbafan.mr@iums.ac.ir

**Web page address**

http://iph.iums.ac.ir/

**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

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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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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

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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**