Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The comparison of the effect of Agomalatin and Placebo on symptoms of obsession in resistant obsessive compulsive disorder patients

Protocol summary

Study aim
Evaluation of the effect of agomelatin on patients with resistant obsessive compulsive disorder

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. NCSS (Number Cruncher statistical system) software and block random method are used to randomize the study.

Settings and conduct
Sixty patients with obsessive-compulsive disorder who have been referred to Ibn Sina Psychiatric Hospital(Shiraz, Iran) will be included in the study during 2020. Physicians, patients, and drug deliverer will blind to the allocation of intervention. It should be noted that the drugs' containers is the same. Additionally, placebo tablet is similar to agomelatine tablet regarding the color and shape

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with refractory obsessive-compulsive disorder whose have Y-BOCS questionnaire score is higher than 15; have no other psychiatric disorder. Exclusion criteria: pregnancy; use of the concomitant psychotherapy.

Intervention groups
Intervention group: 25 mg of agomelatine tablets per night + sertraline 100 mg daily for 12 weeks. Control group: placebo tablets per night+ sertraline 100 mg daily for 12 weeks

Main outcome variables
Severity of obsession based on Y-BOCS questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190726044339N3**
Registration date: **2020-12-23, 1399/10/03**
Registration timing: **registered_while_recruiting**
Last update: **2020-12-23, 1399/10/03**
Update count: **0**

Registration date
2020-12-23, 1399/10/03

Registrant information

Name
Seyed Hamdollah Mosavat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3725 4105

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hamdi_88114@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the effect of Agomalatin and Placebo on symptoms of obsession in resistant obsessive compulsive disorder patients

Public title
The effect of Agomalatin on resistant obsessive compulsive disorder patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with resistant obsessive-compulsive disorder who have not taken any medication for 3 months before the start of the study Score of the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) above 15
Exclusion criteria:
Having other psychiatric disorder Pregnancy and lactation Having Hepatic disorder Receive concomitant psychotherapy

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher will enroll participants based on convenience sampling method. NCSS software (Number Cruncher Statistical System) and block randomization method will be used for randomization in the study. In the block randomization method, participants will categorize into 6 blocks (AABB, ABAB, BBAA, BABA, ABBA, BAAB), each block containing 4 participants. In this study, "A" will assign to the drug group and "B" to the placebo group, for example: in the "ABAB" block, the first person enters the drug group, the second person enters the placebo group, the third person enters the drug group, and the fourth person enters the placebo group. Thus, all eligible participants will randomly be assigned to one of the study arms according to the randomization list.

Blinding (investigator's opinion)
Double blinded

Blinding description
Physicians, patients, and drug deliverer will blind to the allocation of intervention. It should be noted that the drugs' containers is the same. Additionally, placebo pill is similar to agomelatin pill regarding the color and shape

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Ibn Sina Hospital; Hafez street
City
Shiraz
Province
Fars
Postal code
7134845794

Approval date
2020-04-16, 1399/01/28

Ethics committee reference number
IR.SUMS.MED.REC.1399.039

Health conditions studied

1

Description of health condition studied
obsessive-compulsive disorder (OCD)

ICD-10 code
F42

ICD-10 code description
Obsessive-compulsive disorder

Primary outcomes

1

Description
Obsession severity

Timepoint
At the beginning of the study and at the 12th week

Method of measurement
Yale-Brown Obsessive Compulsive Scale (Y-BOCS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: agomelatin 25 mg one tablet per night with 100 mg of sertraline daily for 12 weeks

Category
Treatment - Drugs

2

Description
Control group: One placebo tablet every night with a daily intake of 100 mg of sertraline for twelve weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ibn Sina Psychiatric Hospital
Full name of responsible person
Amir Bazafshan
Street address
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Sponsors / Funding sources

1

Sponsor

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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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available