Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effect of adding Agomelatine to Escitalopram in the treatment of major depressive disorder

Protocol summary

Study aim
Determining the effect of adding agomelatine to Escitalopram in the treatment of major depressive disorder

Design
In this double-blind phase 3 clinical trial study, 70 patients with major depressive disorder were distributed in to two groups of 35 by using simple random allocation method.

Settings and conduct
This clinical trial study was performed in 1400 in psychiatric clinics affiliated to Shahid Sadoughi University of Medical Sciences in Yazd. The study is a double-blind and patients and the person evaluating the outcome of treatment are unaware of the type of drug received.

Participants/Inclusion and exclusion criteria
In this study, patients with major depressive disorder who agree to participate in the study and are in the age range of 18 to 65 years are included in the study. Patients with a history of underlying disease, drug addiction and illiteracy are not included in the study.

Intervention groups
70 patients with major depressive disorder are divided into two groups of 35 patients. In the first group, 25-50 mg of oral Agomelatine was given as a single daily dose and 10-20 mg of oral Escitalopram as a single daily dose for 12 weeks and in the second group, 10-20 mg of oral Escitalopram as a single daily dose. It is given with a placebo that is similar to Agomelatine at the same dose and duration.

Main outcome variables
Treatment of major depressive disorder

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130311012782N52**
Registration date: **2021-02-24, 1399/12/06**
Registration timing: **prospective**

Last update: **2021-02-24, 1399/12/06**
Update count: **0**

Registration date
2021-02-24, 1399/12/06

Registrant information
Name
Ali Mehrabi kushki
Name of organization / entity
Isfahan University of Medical Sciences
Country
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-04, 1400/01/15
Expected recruitment end date
2022-03-16, 1400/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of adding Agomelatine to Escitalopram in the treatment of major depressive disorder

Public title

The effect of adding Agomelatine to Escitalopram in the treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Major Depressive Disorder Patient consent to participate in the study range age between 18-65 years Minimum literacy Has suitable conditions for completing the questionnaire

Exclusion criteria:

Drug addiction Having medical and underlying disease Major changes in diet regimen in recent months Existence of verbal and hearing problems

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation patients between two groups will be done by simple random allocation method. To do this, 70 cards with 35 letters A on them and 35 letters B on the other 35 were prepared and placed in a box and shuffled well. Patients are initially asked to take a card out of the box. Depending on the letter written on the card, patients enter the first group (letter A) or the second group (letter B).

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding is that patients are unaware of the type of medication they are receiving. The drug is prescribed by the researcher, but the outcome of the treatment is reviewed by an experienced psychiatrist who is unaware of the type of medication the patient is receiving.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Research faculty, Shahid sadoughi University of medical sciences, shohadaye gomnam street

City

Yazd

Province

Yazd

Postal code

8434193474

Approval date

2019-11-21, 1398/08/30

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.305

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32:

ICD-10 code description

Major Depressive Disorder

Primary outcomes

1

Description

treatment of Major Depressive Disorder

Timepoint

Every month

Method of measurement

Hamilton questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Receive 25-50 mg oral Agomelatine of Abidi Pharmaceutical Company as a single daily dose and 10-20 mg of oral Escitalopram made by abidi Pharmaceutical Company as a single daily dose for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: Receive 10-20 mg of oral Escitalopram in a single daily dose with placebo, which is prepared similar to agomelatine and is given at the same

dose and duration.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Psychatry clinic, Shahid Sadoughi hospital

Full name of responsible person
Hosein Azadi

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Psychiatry clinic, Shahid Sadoughi hospital, Shohadaye gomnam street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Masoud Mirzaei

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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Reza Bidaki

Position
Resident

Latest degree
Specialist

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Psychiatrics

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Person responsible for updating data

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Position
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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
The plan belongs to a government agency and cannot be shared

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available