

# 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

Iran (Islamic Republic of)

###### Phone

+98 31 3629 1510

###### Email address

mehrabi@mui.ac.ir

##### 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**

Psychiatry clinic, Shahid Sadoughi hospital

**Full name of responsible person**

Hosein Azadi

**Street address**

Psychiatry clinic, Shahid Sadoughi hospital,  
Shohadaye gomnam street

**City**

Yazd

**Province**

Yazd

**Postal code**

8434193474

**Phone**

+98 31 3669 2174

**Email**

reza.bidaki111@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaei

**Street address**

Research faculty, Shahid Sadoughi university of  
Medical Sciences, Shohadaye gomnam street

**City**

Yazd

**Province**

Yazd

**Postal code**

8434193474

**Phone**

+98 35 3726 3733

**Email**

M\_mirzaei@gmail.com

**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

**Other areas of specialty/work**

Psychiatrics

**Street address**

Department of Psychology, Shahid sadoughi hospital,  
Shohadaye gomnam street

**City**

Yazd

**Province**

Yazd

**Postal code**

8434193474

**Phone**

+98 35 3726 3733

**Email**

reza.bidaki111@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Reza Bidaki

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Department of Psychology, Shahid Sadoughi hospital,  
Shohadaye gomnam street

**City**

Yazd

**Province**

Yazd

**Postal code**

8434193474

**Phone**

098 35 37263733

**Email**

reza.bidaki111@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Mehrabi

**Position**

Statistical Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Research faculty, Isfahan University of Medical Sciences, Hezarjerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8434193474

**Phone**

+98 31 3669 2174

**Email**

al.mehrabi@gmail.com

## 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