Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy comparison of Agomelatin and sertralin on depressive episode, in patients with bipolar I disorder

Protocol summary

Study aim

Comparison of the efficacy of sertraline and agomelatine on the depressive phase of bipolar I patients

Design

A clinical trial with a control group with a double-blind and random intervention group in phase 3, on 30 patients, where the intervention group with the letter A and the control group with the letter B are randomly separated.

Settings and conduct

It is performed in Kashan and in the office of the main researcher and among the patients referred to the psychiatric hospital and introduced from the psychiatrist's office. Patients are informed about the research and the type of drug used and explain the existence of a control group without knowing whether it is in the main intervention group or in the control group and that the researcher himself is unaware of the contents of the packages and people in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Bipolar I patients in the depressive phase, people 18 to 65 years old with bipolar depression, no other mental problems, no medication in the last 3 months No entry criteria: Psychotic, manic, pregnant and lactating patients, and people with suicidal ideation

Intervention groups

The intervention group is treated with Agomelatine, which is monitored regularly after starting the drug, and during the face-to-face visits and telephone calls, the treatment process and clinical changes, as well as the possible occurrence of side effects, are closely monitored. In the control group, they also receive Sertraline and are monitored and controlled with the same accuracy as the intervention group.

Main outcome variables

The rate of decrease in depression score - Hamilton score - in the two groups treated with sertraline is different from the group treated with agomelatine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200803048284N1**
Registration date: **2020-11-04, 1399/08/14**
Registration timing: **retrospective**

Last update: **2020-11-04, 1399/08/14**
Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Hamidreza Vojgani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5533 4489

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-27, 1399/07/06

Expected recruitment end date

2020-10-31, 1399/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy comparison of Agomelatin and sertralin on depressive episode, in patients with bipolar I disorder

Public title

Comparison of the effect of Agomelatine and Sertraline on bipolar depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Patients with bipolar I disorder in the depression phase based on the Hamilton scale and clinical interview based on the criteria of the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) Age: 65-18 No liver disease or no impaired liver test. Do not consume drugs and alcohol - Do not have serious neurological problems (epilepsy, dementia, multiple sclerosis, cerebrovascular accidents) and other psychiatric disorders (obsessive-compulsive disorder or anxiety disorders and post-traumatic stress disorder)

Exclusion criteria:

Existence of psychotic manifestations Existence of mania demonstrations Patients with suicidal ideation Pregnancy and lactation

Age

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

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In our study, the two groups of participants selected by the researcher of the project, and the caregiver and executor are unaware of which group of participants are receiving what kind of medicine, so that after selecting people and dividing them into two groups, the drug The same packages in size and shape, distinguished by the Latin letters A&B, are provided to the participating groups by the caretaker, who is also unaware of the contents of the packages.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan, km 3, Qutb Ravandi Blvd., Physician Blvd.

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2020-07-27, 1399/05/06

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.060

Health conditions studied

1

Description of health condition studied

Bipolar Depression I

ICD-10 code

F31/4

ICD-10 code description

Bipolar Depression I

Primary outcomes

1

Description

Improve depressive symptoms and depression score based on the Hamilton scale

Timepoint

Depression scores are measured on a Hamilton scale at baseline and before medication, as well as at 2,4,6,8 weeks.

Method of measurement

Using the Hamilton scale

Secondary outcomes

empty

Intervention groups

1

Description

Bipolar I patients who are in a depressive phase and are being treated with Agomelatine are given Agomelatine tablets from Tadbir Kala Pharmaceutical Company at a

dose of 25 mg only at bedtime for 8 weeks along with one 500 mg Rahakin tablet from Raha Daroo company or 600 mg (two 300 mg tablets) lithium carbonate from Alhawi Pharmaceutical Company is given orally at bedtime.

Category

Treatment - Drugs

2

Description

Bipolar I patients who are in the depressive phase and are treated with Sertraline are given orally for 8 weeks Sertraline tablets from Dr. Abidi Pharmaceutical Company at a dose of 50 mg daily along with one 500 mg Rahakin tablet from Raha Daroo company or 600 mg (two 300 mg tablets) lithium carbonate from Alhawi Pharmaceutical Company is given orally at bedtime.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Afshin Ahmadvand's office

Full name of responsible person

Dr. Afshin Ahmadvand

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Vajgani

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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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
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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