Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparing the effectiveness of Agomelatine and Sertraline in the treatment of patients aged 18 to 65 years with major depression disorder

Protocol summary

Study aim
Comparing the effectiveness of Agomelatine and Sertraline in the treatment of patients aged 18 to 65 years with major depression disorder

Design
A randomized clinical trials with parallel groups (Agomlatin and Sertraline), double-blind performed on 52 patients with major depression. Randomization will be done through block randomization method.

Settings and conduct
The place of the study is the clinic of Kargarnejad Psychiatric Hospital in Kashan. In this double blind study, both the patient and the assessor physician are kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with major depressive disorder; Age of 18 to 65 years. Non-inclusion criteria: pregnancy and lactation; History of bipolar and other psychiatric disorders; Patients with suicidal ideation; Use of other antidepressants; liver diseases.

Intervention groups
Intervention Group 1: Agomlatin is administered 25 to 50 mg daily for 8 weeks. Intervention Group 2: Sertraline is prescribed 50 to 200 mg daily for 8 weeks.

Main outcome variables
Depression score in Hamilton's questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200407046977N1**
Registration date: **2020-07-07, 1399/04/17**
Registration timing: **retrospective**

Last update: **2020-07-07, 1399/04/17**
Update count: **0**

Registration date
2020-07-07, 1399/04/17

Registrant information
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Marzieh Barati kariznoo
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-21, 1398/09/30

Expected recruitment end date
2020-04-18, 1399/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of Agomelatine and Sertraline in the treatment of patients aged 18 to 65 years with major depression disorder

Public title
The effect of Agomellatin with sertraline in patients with major depression

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 65-18 years old Patients with major

depression based on the Hamiltonian scale and clinical interview based on the DSM5 criteria

Exclusion criteria:

Pregnancy and lactation History of bipolar disorder and other psychiatric disorders Use of other antidepressants Patients with suicidal ideation Liver disease or impaired liver function test

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Since it was possible that the members of each group could not be equal due to probability, using the quadruple block, all the probabilities of selecting individuals in groups were considered as AABB, ABAB, BAAB, BABA, BBAA, ABBA.Each group of four patients is randomly selected from one of the above blocks and individuals are assigned to one of groups A or B, respectively (Permuted block randomization method)

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications are placed in similar envelopes labeled A or B so that the patient is unaware of the prescribed medication. A psychiatrist visits the patient and prescribes medication, and another psychiatrist who is unaware of the treatment assigned to the patient evaluates the treatment results with Hamilton scales.

Placebo

Not used

Assignment

Parallel

Other design features

The study questinnaire was developed in 1960 by Hamilton to assess the severity of depression by a therapist. A standard, semi-structured questionnaire for assessing depression includes 24 questions and scores from 0 to 50. The questionnaire measures various aspects of depression (behavioral, physical, cognitive, emotional, emotional, hypochondriac, sexual issues, suicide, and sleep disorders). Grades 13-8 are mild depression, 18-18 are moderate depression, 19-22 are severe, and 23 and above are very severe. A score below 7 indicates no depression. This questionnaire has a satisfactory validity and very good reliability (9). In 2000, Gharaei, Houshang Mehryar and Mehrabi reported the reliability coefficient of this scale using 0.85 and 0.89 retesting methods.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kashan University of Medical Sciences

Street address

Kargarnejad Hospital; Kashan University of Medical Sciences; Ghotbe Ravandi bulevard

City

Kashan

Province

Isfehan

Postal code

8715973446

Approval date

2020-03-15, 1398/12/25

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.139

Health conditions studied

1

Description of health condition studied

Major depression disorder

ICD-10 code

F33.9

ICD-10 code description

Major depressive disorder, recurrent, unspecified

Primary outcomes

1

Description

Depression score in the Hamilton questionnaire

Timepoint

At the beginning of the study (week 0) and weeks 2, 4, 6, and 8 after the intervention

Method of measurement

Hamilton Depression Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Prescribing Agomlatin from Tadbir Kala Company with a daily dose of 25 to 50 mg for 8 weeks.

Category

Treatment - Drugs

2

Description
Control group: Sertralin tablet 50 mg/ Daily, manufactured by Abidi co.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Kargarnejad psychiatric hospital
Full name of responsible person
Dr. Afshin Ahmadvand
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Kargarnejad hospital; Kashan University of Medical Sciences; Ghotbe Ravandi bulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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
Ethical considration
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