Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The comparison of the efficacy of Agomelatine and Sertraline in treatment of depression symptoms in patients with heart failure in double-blind randomized clinical trial

Protocol summary

Study aim
Comparison of the efficacy of Agomelatine and Sertraline in treatment of depression symptoms in patients with heart failure

Design
Clinical trial without control group, with parallel groups, double-blind, randomized, 58 patients with a block size of 4 will be randomly assigned to two groups of 29 people.

Settings and conduct
The studied population is patients over 18 years of age who refer to the heart failure clinics of Babol University of Medical Sciences. Patients will be randomly divided into 2 intervention groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years, With heart failure, Willingness to participate in the study, depressive disorder based on the questionnaire Exclusion criteria: Patient with cognitive impairment, Mental retardation, History of substance use, Bipolar disorder, Kidney/Liver failure, Any uncontrolled medical illness

Intervention groups
Intervention group 1: Treatment with sertraline (Soban Co) starts as a daily tablet with a dose of 50 mg, which can be increased up to a maximum of 200 mg according to the clinical response and side effects. Intervention group 2: Treatment with agomelatine (Tekaje Co) is started as a daily tablet with a dose of 25 mg, which can be increased up to a maximum of 50 mg according to the clinical response and side effects.

Main outcome variables
Patient´s depressive condition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170606034348N7**
Registration date: **2022-12-26, 1401/10/05**
Registration timing: **prospective**

Last update: **2022-12-26, 1401/10/05**
Update count: **0**

Registration date
2022-12-26, 1401/10/05

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 121 3171

Email address
a.hamidia@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-20, 1401/10/30

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the efficacy of Agomelatine and Sertraline in treatment of depression symptoms in patients with heart failure in double-blind randomized

clinical trial

Public title
Treatment of depressive symptoms in patients with heart failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years old With heart failure Depressive Disorder (Based on the questionnaire) Willingness to participate in the study
Exclusion criteria:
Patient with cognitive impairment Mental retardation History of substance use Bipolar disorder Kidney/Liver failure Any uncontrolled medical illness
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two groups of 29 people using blocks of 4 and a ratio of 1:1. Randomization will be done using Statistics and Sample Size android software. In order to hide the treatment process, each drug is assigned a random code corresponding to the sequence generated above, and only the random code is written on the cans of the drugs. After entering the patients into the study and assigning treatment to them, the code inserted on the medicine will be recorded on the patient's file.
Blinding (investigator's opinion)
Double blinded
Blinding description
Agomelatine (Tekaje Company) and Sertraline (Soban Company) are prepared and coded in identical containers without name labels, and are provided to the researcher based on random allocation by the design statistician. Therefore, none of the patients and the researcher will know about the assigned treatment and will not know until the end of the study. The opening of the codes is done at the end of the study or in special cases with the diagnosis of the treating doctor (in case of severe drug side effects) during the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2022-12-14, 1401/09/23
Ethics committee reference number
IR.MUBABOL.REC.1401.138

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32.0
ICD-10 code description
Major depressive disorder, single episode, mild

Primary outcomes

1

Description
patient´s depressive condition
Timepoint
Before intervention (first visit) ,the end of the fourth week (second visit), the end of the eighth week (third visit), the end of the twelfth week (the fourth visit)
Method of measurement
BDI and Hamilton Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Sertraline group patients (Soban company) will receive one 50 mg tablet daily (depending on the patient's response, it is possible to increase the

dose up to a maximum of 200 mg).

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients in the agomelatine group (Tekaje company) will receive one 25 mg tablet daily (depending on the patient's response, it is possible to increase the dose up to a maximum of 50 mg).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid specialized and super-specialized clinic of Babol

Full name of responsible person

Dr. Angela Hamidia

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Daneshgah Square, Ganjafrooz Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Angela Hamidia

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Dr. Angela Hamidia

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Latest degree

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Person responsible for updating data

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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 plan to release it yet.
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