

# 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

**Street address**

Daneshgah Square, Ganjafrooz Avenue

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**Web page address****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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Shahid Yahyanejad hospital, Jomhoory Eslami street

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

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**Position**

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## Person responsible for updating data

### 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**  
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**City**  
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**Province**  
Mazandaran

## 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