Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the effectiveness of Escitalopram and Bupropion in treatment of depression symptome patient with heart failure in double blind randomized clinical trial

Protocol summary

Study aim
Determining the comparative effectiveness of escitalopram and bupropion in the treatment of depression in patients with heart failure

Design
Clinical trial without control group, with parallel groups, double-blind, randomized, 80 patients with a block size of 4 will be randomly assigned to two groups of 40 people

Settings and conduct
The studied population is patients over 18 years of age referring to heart failure clinics of Babol University of Medical Sciences. Patients will be randomly divided into 2 intervention groups. The first intervention group is Bupropion treatment group and the second intervention group is Escitalopram treatment group. Bupropion and Escitalopram are prepared and coded in completely similar containers without name labels, which are prepared and coded in the same color and smell, and are provided to the researcher based on random allocation by the statistician of the project. Patients will be visited four times.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years, heart failure, willingness to participate in the research, depression disorder according to the questionnaire, exclusion criteria: patient with cognitive impairment, mental retardation, history of drug use, bipolar disorder, History of depression before heart failure, history of seizures

Intervention groups
Intervention group 1: Bupropion (Zibutrin) (Tehran Daru pharmaceutical group) (75 mg) starts as 1 tablet daily (which can be increased up to a maximum of 150 mg according to the clinical response and side effects)
Intervention group 2: Citalopram Tekaje drug group (5 mg) starts as 1 tablet daily (which can be increased up to a maximum of 20 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: **IRCT20190525043700N5**
Registration date: **2022-12-29, 1401/10/08**
Registration timing: **prospective**

Last update: **2022-12-29, 1401/10/08**
Update count: **0**

Registration date
2022-12-29, 1401/10/08

Registrant information

Name
Romina Hamzehpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3229 1951

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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of Escitalopram and Bupropion in treatment of depression symptome patient 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 History of depression before heart failure History of seizure
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two groups of 40 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
Bupropion (Zibutrin) (Tehran Daro Pharmaceutical Group) and Citalopram (Takajeh Pharmaceutical Group) in completely similar containers without name labels, which are prepared and coded in the same color and smell, and are provided to the researcher based on random allocation by the project statistics expert. Takes. Therefore, none of the patients and the researcher will know about the assigned treatment and will not know until the end of the study. Codes are opened at the end of the study or in special cases with the diagnosis of the treating physician (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
2022-08-15, 1401/05/24
Ethics committee reference number
IR.MUBABOL.REC.1401.085

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
Beck's depression inventory and Hamilton Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in the treatment group with Bupropion (Zibutrin) (Tehran Daru Pharmaceutical Group) (75mg) start as 1 tablet daily (which can be increased up to 150mg according to the clinical response and side effects)
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in the es citalopram treatment group (Takaje drug group) (5 mg) start as 1 tablet daily (which can be increased up to a maximum of 20 mg according to the clinical response and side effects)
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. Romina Hamzehpour
Street address
Omid specialized and subspecialty clinic, west side of Rouhani Hospital, Ganj Afrooz St
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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
Romina Hamzehpour
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available