

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of treatment with escitalopram on quality of life and hospitalization rate in depressed patients with systolic heart failure: a double blind randomized controlled trial

Protocol summary

Study aim

evaluation the effect of pharmacologic treatment of depression on the short-term prognosis of depressed patients with systolic heart failure

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 84 patients. The rand function of Excel software was used for randomization

Settings and conduct

The participants in the study at Imam Hossein Hospital in Tehran will complete the Hospital Anxiety and Depression Scale, the Patient Health Questionnaire, and the Minnesota Quality of Life Questionnaire. one group will be treated with citalopram at the rate of 20 mg for 8 weeks and the other group will be treated with placebo. Then the follow-up of the patients will be done along with physical examination again, and answering the quality of life questionnaire again after 8 weeks. .In screening, clinical history, physical examination and left ventricular systolic function will be evaluated. This study is double-blind. . The people participating in the study and the evaluators of the final outcome of the patients will not be aware of the drug or placebo.

Participants/Inclusion and exclusion criteria

The study population: includes patients referred to Imam Hossein Hospital in 1401-1402 who were admitted to the CCU department and had systolic heart failure and depression in the evaluations

Intervention groups

After checking the entry conditions of the participants in the study according to the entry and non-entry criteria, the candidate will be placed in one of the following 2 groups using a pre-planned random allocation: Intervention group: taking 20 mg of S-citalopram orally manufactured by Abidi company for 8 weeks from the beginning of the study. Placebo group: placebo

consumption of orally manufactured by Abidi company for 8 weeks from the beginning of the study.

Main outcome variables

Quality of life, hospitalization rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230510058142N1**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **retrospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

Registration date

2023-12-09, 1402/09/18

Registrant information

Name

Farnaz Pourrajab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3431 4130

Email address

farnazpourrajab71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of treatment with escitalopram on quality of life and hospitalization rate in depressed patients with systolic heart failure: a double blind randomized controlled trial

Public title
The effect of treatment with escitalopram on quality of life and hospitalization rate in depressed patients with systolic heart failure

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 People aged 30 to 75 years Patients with left ventricular systolic dysfunction (left ventricular ejection fraction <0.40) Clinical diagnosis of heart failure with at least one episode of dyspnea either with minimal activity or at rest NYHA classIII or IV Informed consent of patients
Exclusion criteria:
 Previous history of intolerance to SSRI antidepressants Bipolar or severe personality disorder Severe suicidal thoughts Recent dependence on alcohol or drugs pregnancy breastfeeding

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
All eligible people will be randomly assigned to one of the two groups to receive medicine or placebo with a ratio of 1:1. Randomization will be done automatically by creating random numbers in an Excel file and assigning people to two drug and placebo groups.The rand function of Excel software was used for randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind. The medicine and placebo needed for the people participating in the study will be completely covered and indistinguishable form for use by patients. The people participating in the study and the evaluators of the final outcome of the patients will not be

aware of the drug or placebo. The grouping of patients will be done based on the allocation of random numbers in the Excel file prepared by the researcher responsible for the study, and other people and patients will not know about the grouping

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shahid beheshti University of Medical Sciences
Street address
 Zarafshan Ave, Qods Town,Tehran
City
 Tehran
Province
 Tehran
Postal code
 1985717443
Approval date
 2023-05-02, 1402/02/12
Ethics committee reference number
 IR.SBMU.MSP.REC.1402.047

Health conditions studied

1

Description of health condition studied
 heart failure
ICD-10 code
 I50
ICD-10 code description
 Heart failure

Primary outcomes

1

Description
 quality of life
Timepoint
 At the beginning of the study and 8 weeks later
Method of measurement
 Minnesota Standard Questionnaire

Secondary outcomes

1

Description

Hospitalization rate

Timepoint

The beginning of the study and 2 month later

Method of measurement

Patient files and Questionnaire

Intervention groups

1

Description

Intervention group: Taking 20 mg of es citalopram orally, manufactured by abidi company, for 8 weeks from the beginning of the study then Refer to a psychiatrist after the end of the study to continue antidepressant treatment

Category

Treatment - Drugs

2

Description

Control group: Taking placebo for 8 weeks, referring patients to a psychiatrist after the end of the intervention to start anti-depressant treatment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

farnaz pourrajab

Street address

Imam Hossein Hospital, Shahid Madani Street, Tehran

City

Tehran

Province

Tehran

Postal code

6314116177

Phone

+98 21 7343 3000

Email

farnazpourrajab@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr afshin zarghi

Street address

Shahid Madani Ave, Imam Hossein hospital , Tehran

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Email

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

farnaz pourrajab

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Shahid Madani Ave, Imam Hossein hospital, Tehran

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Person responsible for scientific inquiries

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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