# 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
**City**
Tehran
**Province**
Tehran
**Postal code**
6314116177
**Phone**
+98 21 7343 3000
**Email**
farnazpourrajab71@gmail.com
**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
**Street address**
Shahid Madani Ave, Imam Hossein hospital, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
6314116177
**Phone**
+98 21 7343 3000
**Email**
farnazpourrajab71@gmail.com

## Person responsible for scientific 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

**Street address**
Shahid Madani Ave, Imam Hossein hospital,Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
6314116177

**Phone**
+98 21 7343 3000

**Email**
farnazpourrajab71@gmail.com

## Person responsible for updating data

**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

**Street address**
Shahid Madani Ave,Imam Hossein hospital , Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
6314116177

**Phone**
+98 21 7343 3000

**Email**
farnazpourrajab71@gmail.com

## 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