

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of ivabradine on the quality of life in patients with heart failure with reduced ejection fraction: a double-blind, placebo-controlled randomized clinical trial

Protocol summary

Study aim

Studying the effect of Ivabradine on the quality of life patients with heart failure with reduced EF

Design

Randomized clinical trial, double-blind, placebo-controlled, phase 3 clinical trial on 90 patients. Random Allocation software was used for randomization.

Settings and conduct

This study will be conducted on patients over 18 years of age with heart failure with reduced ejection fraction, regardless of gender, who are referred to Shahid Madani Hospital in Tabriz. It is a placebo-controlled trial involving 90 patients, who will be randomly assigned to either the drug or placebo group using block randomization. The study is designed as a double-blind trial, meaning that neither the participants nor the researchers will be aware of whether the administered treatment is the actual drug or a placebo. The drug and placebo tablets will be identical in shape, size, color, taste, and packaging.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of heart failure with reduced EF less than 35%, over 18 years of age, use of the maximum dose of beta-blocker or the maximum tolerated dose, sinus rhythm on electrocardiogram, heart rate above 70 bpm, and having informed consent for participation in the study; Exclusion criteria: not having consent for participation in the study, pregnancy, and having any comorbid condition that significantly impairs quality of life

Intervention groups

The intervention group will receive Ivabradine tablets (5 mg every 12 hours) for one month in addition to their routine treatments to evaluate its effect on their quality of life. The control group will receive placebo tablets (identical in appearance, every 12 hours) for one month in addition to their routine treatments to assess its impact on their quality of life.

Main outcome variables

Quality of life score based on Minnesota Living with Heart Failure Questionnaire (MLHFQ)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250518065795N1**

Registration date: **2025-07-07, 1404/04/16**

Registration timing: **prospective**

Last update: **2025-07-07, 1404/04/16**

Update count: **0**

Registration date

2025-07-07, 1404/04/16

Registrant information

Name

Reza Noori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3232 2057

Email address

dr.noori_r@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-11, 1404/06/20

Expected recruitment end date

2025-10-12, 1404/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of ivabradine on the quality of life in patients with heart failure with reduced ejection fraction: a double-blind, placebo-controlled randomized clinical trial

Public title

The effect of ivabradine on the quality of life in patients with heart failure with reduced ejection fraction

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

A confirmed diagnosis of heart failure with reduced ejection fraction with an ejection fraction of less than 35% Use of the maximum dose of beta-blocker or the maximum tolerated dose Sinus rhythm on electrocardiogram Heart rate above 70 bpm Informed consent for participation in the study At least 18 years old

Exclusion criteria:

Not having consent for participation in the study Pregnancy Having any comorbid condition that impairs quality of life

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a double-blind, placebo-controlled randomized clinical trial. Patients will be assigned to either the intervention or placebo group using "Block Randomization" based on computer-generated numbers produced by the "Random Allocation" software. In this software, the total number of groups and total sample size will be defined, then within each block, the randomization option will be executed. Next, a list of computer-generated numbers will be provided to the physician, and the physician will allocate patients to the groups according to the sequence determined by the software for group assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blinded The participants, the principal investigator, healthcare personnel (physicians and

nurses), data collectors, and outcome assessors

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Ave., Tabriz, Iran.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616441

Approval date

2025-04-28, 1404/02/08

Ethics committee reference number

IR.TBZMED.REC.1404.115

Health conditions studied**1****Description of health condition studied**

Heart failure with reduced ejection fraction

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

Primary outcomes**1****Description**

Quality of life score

Timepoint

At baseline (before the start of the intervention) and one month after initiation of treatment

Method of measurement

Minnesota Living with Heart Failure Questionnaire (MLHFQ)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive Ivabradine tablets (5 mg every 12 hours) for one month in addition to their routine treatments to evaluate its effect on their quality of life.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive placebo tablets (identical in appearance, every 12 hours) for one month in addition to their routine treatments to assess its impact on their quality of life.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Shahid Madani Hospital

Full name of responsible person

Reza Noori

Street address

Shahid Madani Hospital., Daneshgah Ave., Tabriz, Iran.

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5163639889

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dr.noori_r@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Khosro Adibkia

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adibkia@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Reza Noori

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Taban Sadeghi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Reza Noori

Position

Resident

Latest degree

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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