Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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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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

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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

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Full name of responsible person
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Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
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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