Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of Ranolazine added to standard treatment to control angina pectoris in patients with coronary artery bridge who underwent angiography in Alzahra Heart Hospital, Shiraz during 2023 and 2024

Protocol summary

Study aim

Investigating the effect of adding Ranolazine to standard treatment to control angina pectoris in patients with coronary artery bridge

Design

Clinical Trial Prospective study, Randomized, Parallel group, double-blinded, phase 3, 52 patients

Settings and conduct

Location: Alzahra heart hospital, Shiraz Setting: After registration In the study, patients will be randomly divided into two groups. A group of participants will be given beta blocker for 6 months and for the other group of participants beta blocker and Ranolazine 500 mg (twice daily) will be given. After six months, patients in both groups will be re-evaluated and checked for symptomatic and functional process and the results will be compared. All investigators, patients, and follow-up team members were unaware of the treatment allocation, making the study unbiased and controlled.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over18 years old; no renal/liver failure; willing to participate; dyspnea or angina at rest or on exertion; no coronary artery disease. Exclusion criteria: long QT interval; using CYP3A inhibitors; using medication that prolong the QT interval; pregnancy/lactation; Parkinson's disease; life expectancy less than 6 months.

Intervention groups

Control group (26 people): beta blocker will be given. Intervention group (26 people): beta blocker and Ranolazine 500 mg (orally twice daily) will be given.

Main outcome variables

Severity of angina pectoris

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230801059005N2**
Registration date: **2023-11-08, 1402/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-08, 1402/08/17**
Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Aida Bazrgar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 4196

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-08, 1402/08/17

Expected recruitment end date

2024-05-06, 1403/02/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of Ranolazine added to standard treatment to control angina pectoris in patients with coronary artery bridge who underwent angiography in Alzahra Heart Hospital, Shiraz during 2023 and 2024

Public title
Ranolazine effects on angina pectoris in patients with coronary artery bridge

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian origin No history of organ damage, heart failure or renal failure Willingness to participate in research Angina or dyspnea on exertion or at rest No coronary artery disease (less than 50% stenosis in all epicardial coronary arteries)

Exclusion criteria:
Not willing to keep participating in the trial patients younger than 18 years Liver failure, long QT, renal failure Using CYP3A inhibitors such as Diltiazem, Verapamil, Ketoconazole, Macrolides and protease inhibitors Patient who are using medication that cause QT prolongation Pregnancy or lactation Parkinson's disease Life expectancy less than 6 months

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization, using table of random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
All investigators, patients, and follow-up team members were kept unaware of the treatment assignments throughout the study, ensuring a non-biased controlled study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand Blvd, Shiraz

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2023-06-17, 1402/03/27

Ethics committee reference number
IR.SUMS.MED.REC.1402.290

Health conditions studied

1

Description of health condition studied
Myocardial bridge in coronary arteries

ICD-10 code
Q24.5

ICD-10 code description
Malformation of coronary vessels

Primary outcomes

1

Description
Severity of chest pain

Timepoint
At the beginning- 6 month later

Method of measurement
Seattle Angina Questionnaire (SAQ) and The Duke Activity Status Index (DASI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group, in addition to beta-blocker Bisoprolol Fumarate (Concor) Tablet 2.5 mg daily (Brand: Abidi), Ranolazine Tablet 500 mg daily (Xinaro 500mg) is prescribed for 6 months.

Category
Treatment - Drugs

2

Description
Control group: Bisoprolol Fumarate (Concor) 2.5 mg daily (Brand: Abidi) and Placebo is given to this group for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
shiraz university of medical science
Full name of responsible person
Nasim Kheirandish
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Sponsors / Funding sources

1

Sponsor
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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
Shiraz 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
Shiraz University of Medical Sciences
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Person responsible for updating data

Contact

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general practitioner

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Family Physician

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Only a part of data like primary outcome can be shared.

When the data will become available and for how long
The access period starts 1 year after the publication time of results

To whom data/document is available
This data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data will be made available to researchers for further studies or more advanced analysis.

From where data/document is obtainable
Researchers can send an email regarding the request for the data of our study to Dr. Hamed Bazrafshan. Email: Hamedbazrafshan@yahoo.com

What processes are involved for a request to access data/document
The researchers can request for this study's data through an e-mail one year after the publication data of this study in one of the pee-reviewed journals.

Comments