

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 over 18 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

Email address

aidabazrgar@sums.ac.ir

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
<u>1</u>
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
<u>1</u>
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
<u>1</u>
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
<u>1</u>
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

Street address

shiraz university of medical science, zand street,
shiraz

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Province

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7196855794

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nasim.kheirandish3@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

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zand

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7134814336

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info@sums.ac.ir%20

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

Full name of responsible person

Yaser Rahbarian

Position

Cardiology 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

Shiraz University of Medical Sciences

Full name of responsible person

Hamed Bazrafshan

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nasim Kheirandish

Position

general practitioner

Latest degree

Medical doctor

Other areas of specialty/work

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 peer-reviewed journals.

Comments