Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the antianginal effect of ranolazine versus high-dose nitrocardin on quality of life and symptom control in patients with stable angina pectoris with a history of percutaneous coronary intervention

Protocol summary

Study aim

Study objective: To evaluate the anti-anginal effect of ranolazine compared to high-dose nitroglycerin and its impact on quality of life in patients with stable angina and a history of PCI.

Design

Conducted at Ayatollah Rouhani Hospital, Babol (2024–2025); primary outcomes: frequency of angina attacks, chest pain severity, quality of life; secondary outcomes: blood pressure, heart rate, adverse effects, cardiovascular function; blinding not feasible; data collected periodically and analyzed statistically; sample size of 88 (44 per group) based on G*Power.

Settings and conduct

After ethFollowing ethical approval and informed consent, eligible patients at Omid Clinic were randomized to ranolazine 500 mg twice daily or nitroglycerin 6.4 mg twice daily in addition to baseline therapy; anonymous questionnaires were completed at baseline and after one month, and data were analyzed for outcome measures.

Participants/Inclusion and exclusion criteria

nclusion criteria were age 40–75 years, LVEF ≥ 40%, chronic stable angina ≥ 1 month, at least two weeks of baseline anti-anginal therapy, and safe eligibility for ranolazine. Exclusion criteria included severe heart failure, recent unstable angina or MI, significant arrhythmias, uncontrolled blood pressure, liver or kidney dysfunction, pregnancy or lactation, and inability to cooperate.

Intervention groups

Randomized two-arm clinical trial comparing ranolazine and nitroglycerin in patients with stable angina.

Main outcome variables

Gender: Diabetes mellitus: Ranolazine use: Angina pectoris severity: Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250821066938N1**
Registration date: **2026-04-29, 1405/02/09**
Registration timing: **retrospective**

Last update: **2026-04-29, 1405/02/09**
Update count: **0**

Registration date

2026-04-29, 1405/02/09

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigation of the antianginal effect of ranolazine versus high-dose nitrocardin on quality of life and symptom control in patients with stable angina pectoris with a history of percutaneous coronary intervention

Public title
Investigation of the antianginal effect of ranolazine versus high-dose nitrocardin on quality of life and symptom control in patients with stable angina pectoris with a history of coronary intervention

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient's age is 40 to 75 years. The patient has had chronic angina for at least one month (at least two episodes of anginal pain or discomfort in the chest, jaw, shoulders, back, neck, or arms that is aggravated by activity or emotional stress and relieved by rest or sublingual nitroglycerin, and that occur on two separate days). Patients with a documented history of coronary artery disease (including ≥60% stenosis of at least one major coronary artery on angiography, history of myocardial infarction, or stress-induced reversible ischemia as seen by radionucleotide imaging or echocardiography) and who have undergone angioplasty (percutaneous coronary intervention) at least 6 months after the procedure. Patients with EF (ejection fraction) of at least 40 percent. The patient is being treated with anti-ischemic drugs (beta blockers, calcium channel blockers, long-acting nitrates, ranolazine) for at least 2 weeks. Patients for whom the use of ranolysin is safe and in accordance with the treatment protocol. After explaining the procedure to the patient, consent must be obtained from the patient and his/her family.

Exclusion criteria:
A patient with stable angina who is being treated with nitrates at maximum dose (nitrocardin 6.4mg every 12 hours or once every 8 hours) and whose pain is still not controlled. The patient has NYAH class 3 or 4 heart failure. The patient has a history of myocardial infarction or unstable angina (pain lasting more than 15 to 20 minutes) within the last 2 months. The patient has been referred to the center with acute myocardial infarction or active pericarditis. The patient has undergone coronary artery bypass grafting (CABG) surgery or a decision has been made for CABG in the future. Patients with a history of serious ventricular arrhythmias or QTc prolongation greater than 500 milliseconds. The patient has a history of stroke or transient ischemic attacks within the last 6 months. The patient has uncontrolled blood pressure. The patient has liver disorder with clear clinical evidence (including liver cirrhosis). The patient has severe renal dysfunction (GFR <30ml/min per 1.73m2) or is undergoing renal dialysis treatment. Patients taking drugs that have severe drug interactions with ranolysin (such as ketoconazole, clarithromycin, CYP3A4 inhibitor drugs). Patients who have not tolerated ranolysin in the past for any reason. Patients with inability to cooperate with the study (such as cognitive or psychiatric disorders). Pregnant or breastfeeding women. 1Patients who cannot participate during the study period due to non-medical reasons such as relocation.

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using blocks of 4 and blocks of 22, using the randomizer.org website. Patients will then be randomly assigned to receive ranolazine 500 mg every 12 hours (actoverco) or nitrocardine 6.4 mg twice daily (alborzdarou) in addition to their initial antianginal regimen.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Ganjafrooz Blvd., Babol Town

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴۵

Approval date
2025-05-13, 1404/02/23

Ethics committee reference number
IR.MUBABOL.REC.1404.029

Health conditions studied

1

Description of health condition studied
patients with stable angina

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The outcome variables in this study include changes in the severity and frequency of angina symptoms as well as health-related quality of life. The severity and frequency of angina and the limitation of physical activities will be assessed using the Seattle Angina Questionnaire-7 (SAQ-7), and health-related quality of life will be evaluated using the MacNew Heart Disease Health-related Quality of Life questionnaire.Both questionnaires will be completed by the patients at baseline and at the end of the one-month follow-up period. Total and domain scores of each questionnaire will be calculated, and the changes in these scores between baseline and follow-up will be compared between the two treatment groups.

Timepoint
At two time points: at baseline (before initiation of the intervention) and at the end of the one-month follow-up period after treatment initiation

Method of measurement
Variables will be measured using standardized self-administered questionnaires. Angina frequency, angina burden and physical limitation will be assessed using the Seattle Angina Questionnaire-7 (SAQ-7), and health-related quality of life will be evaluated using the MacNew Heart Disease HRQoL questionnaire.Both questionnaires will be completed by patients at two time points (baseline and at the end of the one-month follow-up). For each patient, total and domain scores will be calculated according to the standard scoring instructions, and changes from baseline will be compared between the two treatment groups

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group will receive Ranolazine 500 mg tablets (manufactured by Actoverco) twice daily (every 12 hours) for one month, in addition to their standard anti-anginal therapy. For patients already taking Nitrates at a dose of 2.6 mg BID (twice daily), this dosage will be maintained without change.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

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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
Babol 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

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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
No - There is not 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
No - There is not 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
No - There is not a plan to make this available