

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigation of the antianginal effect of ranolazine versus high-dose nitroglycerin 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 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

Inclusion criteria were age 40–75 years, LVEF  $\geq$  40%, chronic stable angina  $\geq$  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

##### Name

Saeed Abrotan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 9592

##### Email address

abrotan@yahoo.com

##### 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  $\geq 60\%$  stenosis of at least one major coronary artery on angiography, history of myocardial infarction, or stress-induced reversible ischemia as seen by radionuclide 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  $< 30$ ml/min per  $1.73m^2$ ) 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

#### Name of recruitment center

بیمارستان آیت اله روحانی

#### Full name of responsible person

دکتر سعید ابروتان

#### Street address

Ganj afrooz

#### City

Babol

#### Province

Mazandaran

#### Postal code

۴۷۱۷۶-۴۷۷۴۵

#### Phone

+98 11 3219 9592

#### Email

abrotan@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

رضا قدیمی

##### Street address

Ganj afrooz

##### City

Babol

##### Province

Mazandaran

##### Postal code

۴۷۱۷۶-۴۷۷۴۵

##### Phone

+98 11 3219 9592

##### Email

nfo@mubabol.ac.ir

#### 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

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Babol University of Medical Sciences

**Full name of responsible person**

Saeed Abrotan

**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Ganj afrooz

**City**

Babol

**Province**

Mazandaran

**Postal code**

۴۷۱۷۶-۴۷۷۴۵

**Phone**

+98 11 3219 9591

**Email**

abrotan@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Saeed Abrotan

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Ganj Afrooz

**City**

Babol

**Province**

Mazandaran

**Postal code**

۴۷۱۷۶-۴۷۷۴۵

**Phone**

+98 11 3219 9591

**Email**

abrotan@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Alireza Besharat

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Others

**Street address**

Ganj afrooz

**City**

Babol

**Province**

Mazandaran

**Postal code**

9319613667

**Phone**

+98 51 4261 1544

**Email**

alireza.besharat@gmail.com

**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