

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of the effect of oral Ranolazine on the clinical symptoms of patients with slow flow coronary arteries

Protocol summary

Study aim

Evaluation of the effect of oral Ranolazine on the clinical symptoms of patients with slow flow coronary arteries

Design

Phase 2 randomized double-blinded placebo parallel clinical trial on 48 patients Randomization using www.sealedenvelope.com

Settings and conduct

This study will perform in the heart ward and clinic of Ghaem Hospital in Mashhad. Patients are randomly assigned to Ranolazine and placebo groups. Patients and the main researcher are unaware of groups assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to admission to the study; Age more than 30 years old; Patients with slow coronary flow with a corrected TIMI frame count of more than 27 frames per second Exclusion criteria: Cardiovascular disease other than mild coronary atherosclerosis; intolerance or allergy to Ranolazine; congenital heart disease.

Intervention groups

Intervention group: Receiving common treatments (including aspirin, statins, beta-blockers and ACEIs) + oral Ranolazine 500 mg twice daily for 2 months/ Placebo group: receiving common treatments + placebo tablet once daily for 2 months. Placebo group: Receiving common treatments + placebo tablet twice daily for 2 months.

Main outcome variables

Changes in the score of quality of life according to the EuroQol-VAS (0-100; 100 is the best quality of life and 0 is the worst quality of life); Number of times of pain during the day; Duration of pain (minutes); Pain intensity following activity according to the Canadian Cardiovascular Society (CCS) Grading of Angina Pectoris, all evaluated before intervention and 1, and 2 months after beginning the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054874N6**

Registration date: **2022-09-24, 1401/07/02**

Registration timing: **prospective**

Last update: **2022-09-24, 1401/07/02**

Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Vafa Baradaran Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2301

Email address

baradaranrv@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2024-10-06, 1403/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral Ranolazine on the clinical symptoms of patients with slow flow coronary arteries		Secondary Ids
		empty
Public title	Evaluation of the effect of Ranolazine on patients with slow flow coronary arteries	Ethics committees
Purpose	Treatment	<u>1</u>
Inclusion/Exclusion criteria	Inclusion criteria: Consent to admission to the study Age more than 30 years old Patients who have less than 50% stenosis in each of the 3 main coronary arteries in their coronary angiography and have delayed filling in at least one of the coronary arteries and have slow coronary flow in a corrected TIMI frame count of more than 27 frames per second Exclusion criteria: Intolerance or allergy to Ranolazine History of known congenital heart disease History of any cardiovascular diseases other than mild coronary atherosclerosis	Ethics committee
Age	From 30 years old	Name of ethics committee
Gender	Both	Ethic's committee of School of Medicine, Mashhad University of Medical Sciences
Phase	2	Street address
Groups that have been masked	- Participant - Investigator	Faculty of Medicine, Ferdowsi University complex, Azadi Sq., Mashhad
Sample size	Target sample size: 48	City
Randomization (investigator's opinion)	Randomized	Mashhad
Randomization description	The blocked randomization method is used. The volume of each block will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 12 blocks according to the sample size of 48. Then random numbers between 1 and 12 are selected according to the randomization site Randomaization.com and finally, the treatment allocation list is determined based on the random numbers.	Province
Blinding (investigator's opinion)	Double blinded	Razavi Khorasan
Blinding description	Using sealed envelopes Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B.	Postal code
Placebo	Used	9177948564
Assignment	Parallel	Approval date
Other design features		2022-05-31, 1401/03/10
		Ethics committee reference number
		IR.MUMS.MEDICAL.REC.1401.291
		Health conditions studied
		<u>1</u>
		Description of health condition studied
		Coronary slow flow syndrome
		ICD-10 code
		I20.8
		ICD-10 code description
		Other forms of angina pectoris
		Primary outcomes
		<u>1</u>
		Description
		Changes in the score of quality of life according to the EuroQoL-VAS scale (0-100; 100 is the best quality of life and 0 is the worst quality of life)
		Timepoint
		Before intervention and 1, and 2 months after beginning the intervention
		Method of measurement
		According to the EuroQoL-VAS scale (0-100; 100 is the best quality of life and 0 is the worst quality of life)
		Secondary outcomes
		<u>1</u>
		Description
		Frequent pain during the day
		Timepoint
		Before intervention and 1, and 2 months after beginning the intervention
		Method of measurement

Frequent pain during the day

2

Description

Duration of pain in minutes

Timepoint

Before intervention and 1, and 2 months after beginning the intervention

Method of measurement

Duration of pain in minutes

3

Description

Pain intensity based on activity according to Canadian Cardiovascular Society (CCS) Grading of Angina Pectoris

Timepoint

Before intervention and 1, and 2 months after beginning the intervention

Method of measurement

According to Canadian Cardiovascular Society (CCS) Grading of Angina Pectoris

Intervention groups

1

Description

Intervention group: Patients who have less than 50% stenosis in each of the 3 main coronary arteries in their coronary angiography and have delayed filling in at least one of the coronary arteries and have slow coronary flow in a corrected TIMI frame count of more than 27 frames per second are considered to have slow coronary artery disease. They received routine treatment (including aspirin, statins, beta-blockers and angiotensin-converting enzyme inhibitors) along with oral ranolazine at a dose of 500 mg twice daily for two months.

Category

Treatment - Drugs

2

Description

Control group: Intervention group: Patients who have less than 50% stenosis in each of the 3 main coronary arteries in their coronary angiography and have delayed filling in at least one of the coronary arteries and have slow coronary flow in a corrected TIMI frame count of more than 27 frames per second are considered to have slow coronary artery disease. They received routine treatment (including aspirin, statins, beta-blockers and angiotensin-converting enzyme inhibitors) along with oral placebo tablet with shape, size, and color similar to ranolazine twice daily for two months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital in Mashhad

Full name of responsible person

Dr. Bahram Shahri

Street address

Ghaem hospital, Ahmadabad Blvd, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3801 2739

Email

ShahriB@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour-Mobarhan

Street address

Qurashi Building, Next to Hoveyzeh Cinema, University Street, Mashhad

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Province

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Ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

baradaranrv@mums.ac.ir

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Vafa Baradaran Rahimi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Ghaeem hospital, Ahmadabad Blvd, Mashhad

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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