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 assignation.

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)
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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

Public title

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

Purpose

Treatment

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

Age

From **30 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

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.

Blinding (investigator's opinion)

Double blinded

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.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's committee of School of Medicine, Mashhad University of Medical Sciences

Street address

Faculty of Medicine, Ferdowsi University complex, Azadi Sq., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.291

Health conditions studied

1

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

1

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

1

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
Ghaeem hospital, Ahmadabad Blvd, Mashhad
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Razavi Khorasan
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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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9138813944
Phone
+98 51 3841 1538
Email
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

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

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Person responsible for scientific inquiries

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Position
Assistant professor

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Other areas of specialty/work
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Person responsible for updating data

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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