

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of oral amlodipine on the ischemic chest pain in patients with slow flow coronary arteries

Protocol summary

Study aim

Evaluation of the effect of oral amlodipine on ischemic chest pain in patients with slow coronary blood flow

Design

Phase 2 randomized double-blinded placebo parallel clinical trial on 80 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 amlodipine 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 and sensitivity to amlodipine; congenital heart disease.

Intervention groups

Intervention group: receiving common treatments (including aspirin, statins, beta-blockers and ACEIs) + oral amlodipine 5 mg once daily for 2 months/ Placebo group: receiving common treatments + placebo tablet once daily for 2 months.

Main outcome variables

Pain intensity according to Likert scale 0-10 (10 most pain); 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: **IRCT20220516054874N1**

Registration date: **2022-05-24, 1401/03/03**

Registration timing: **prospective**

Last update: **2022-05-24, 1401/03/03**

Update count: **0**

Registration date

2022-05-24, 1401/03/03

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

2022-06-22, 1401/04/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral amlodipine on the ischemic chest pain in patients with slow flow coronary arteries

Public title

Evaluation of the effect of amlodipine on chest pain

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 sensitivity to amlodipine 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: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization method is used. www.sealedenvelope.com will be used for blocked randomization. In the randomization section of the site, after selecting create a list, it specifies the number of groups, block sizes and the length of the list, and accordingly, presents the list randomization. Allocation Concealment method: sealed envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and the lead investigator are unaware of the study group assignment

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic's committee of Mashhad University of Medical

Sciences

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.014

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**

Pain intensity according to Likert scale 0-10 (10 maximum pain)

Timepoint

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

Method of measurement

According to Likert scale 0-10 (10 maximum pain)

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 amlodipine at a dose of 5 mg once 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 amlodipine once 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

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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 Hoveyze Cinema,
University Street, Mashhad

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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

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

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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