

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Oct 2026

Investigating the effect of Pentoxifylline on echocardiography parameters in patients with coronary slow flow

Protocol summary

Study aim

Evaluating the effect of Pentoxifylline on transthoracic Doppler echocardiography parameters in patients with coronary slow flow

Design

Phase 3 randomized double-blinded placebo parallel clinical trial on 48 patients. Randomization using Randaomaization.com

Settings and conduct

This study will be performed on patients with slow coronary flow in the heart ward of Imam Reza Hospital in Mashhad. Patients are randomly assigned to Pentoxifylline and placebo groups. Randomization will be done using a block method with a block size of 4. The blocked randomization method is used with the volume of each block of four. Sealed envelopes will be used to conceal allocation. A person not involved in sampling and data collection will prepare envelopes and randomize allocation. Due to the use of a placebo similar to the pentoxifylline, 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosing slow flow of coronary arteries based on angiography results; corrected TIMI frame count of more than 27 frames per second; Age older than 18 years; Consent to admission to the study. Not-inclusion criteria: Previous use of pentoxifylline or other methylxanthine drugs; Renal dysfunction with eGFR < 20; Hepatic dysfunction; Body mass index < 18.5; Pregnant or suspected pregnancy.

Intervention groups

Intervention group: Patients with slow coronary flow receiving common treatments along with Pentoxifylline 400 mg three times a day for one month. Placebo group: Patients with slow coronary flow receiving common treatments along with placebo tablets three times a day for one month.

Main outcome variables

Echocardiographic parameters including: Left ventricular ejection fraction, Left Atrial Volume Index, E/e' ratio, diastolic velocities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054874N19**

Registration date: **2024-08-03, 1403/05/13**

Registration timing: **prospective**

Last update: **2024-08-03, 1403/05/13**

Update count: **0**

Registration date

2024-08-03, 1403/05/13

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

2024-08-10, 1403/05/20

Expected recruitment end date

2026-08-11, 1405/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Pentoxifylline on echocardiography parameters in patients with coronary slow flow

Public title

The effect of Pentoxifylline on patients with coronary slow flow

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosing slow flow of coronary arteries based on angiography results corrected TIMI frame count of more than 27 frames per second Age older than 18 years old Consent to admission to the study

Exclusion criteria:

Previous use of pentoxifylline or other methylxanthine drugs Renal dysfunction with GFR < 20 Hepatic dysfunction Body mass index < 18.5 Pregnant or suspected pregnancy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

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 possible 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. Sealed envelopes will be used to conceal allocation. A person not involved in sampling and data collection will prepare envelopes and randomize allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will performed 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**

Research Ethics Committee of Imam Reza Hospital Educational, Research and Treatment Center, Mashhad

Street address

Imam Reza Hospital educational complex building, Imam Reza Hospital, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2024-07-01, 1403/04/11

Ethics committee reference number

IR.MUMS.IRH.REC.1403.091

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**

Echocardiographic parameters including: Left ventricular ejection fraction, Left Atrial Volume Index, E/e' ratio, diastolic velocities

Timepoint

The beginning of the study and one months later

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with slow coronary flow receiving common treatments (including aspirin, statins, beta-blockers and angiotensin-converting enzyme inhibitors) along with Pentoxifylline 400 mg three times a day for one month.

Category

Treatment - Drugs

2

Description

Control group: Patients with slow coronary flow receiving common treatments (including aspirin, statins, beta-blockers and angiotensin-converting enzyme inhibitors) along with placebo tablets three times a day for one month. Placebo will be prepared in the Pharmaceutics Laboratory of Mashhad School of Pharmacy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Cardiology, Imam Reza Hospital

Full name of responsible person

Dr. Javad Ramezani

Street address

Imam Reza hospital, Ebnsina Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

ramezanij@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Qurashi Building, Next to Hoveyze Cinema,

University Street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

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. Behzad Senobari

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Imam Reza Hospital, Ahmadabad Blvd, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

0095 5138012739

Email

senobarib4001@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Behzad Senobari

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Imam Reza hospital, Ahmadabad Blvd, Mashhad

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Province

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Postal code

9177948564

Phone

0095 5138012739

Email

senobarib4001@mums.ac.ir

Person responsible for updating data**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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

0095 5138012739

Email

baradaranrv@mums.ac.ir

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