Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Aspirin, Statin, Nitrate drug regimen on the quality of life in patients with Coronary slow flow disease and its comparison with the addition of Nicorandil

Protocol summary

Study aim

Comparison of the effect of three common drugs (Aspirin, Statin, Nitrate) with three common drugs plus Nicorandil on the quality of life in patients with slow flow coronary syndrome

Design

An open-label randomized controlled clinical trial study with two parallel arms was conducted to evaluate the effectiveness of nicorandil along with the treatment of three common drugs (aspirin, statin, nitrate) in 56 patients with symptomatic Coronary slow flow syndrome. Randomized blocks of 4 are used for randomization. Random allocation software version 2 is used to create random permutations of 4 (random blocks of 4).

Settings and conduct

This clinical trial study is conducted at Bo Ali Sina University Hospital in Qazvin on patients with CSFP. The disease is diagnosed using angiography. Patients were randomly assigned to one of two groups, a three-drug treatment group with 80 mg Aspirin, 20 mg Atorvastatin daily, and 2.6 mg Nitroglycerin every 12 hours, and the three-drug treatment group plus Nicorandil 10 mg every 12 hours. The quality of life in patients is checked at the beginning of the study and then two months after drug treatment using the McNew quality of life questionnaire.

Participants/Inclusion and exclusion criteria

Patients who were candidates for coronary angiography based on clinical symptoms, changes in electrocardiography, echocardiography, myocardial perfusion scan or exercise test, and other causes rather than myocardial ischemia and infarction such as arrhythmia or conduction disorders were included in the study.

Intervention groups

Group of three common drugs regimen (Aspirin, Statin, Nitrate) Group of three common drugs plus nicorandil

Main outcome variables

The primary outcome in this study is the reduction of clinical symptoms and the secondary outcome is the improvement of patient's quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221228056964N1**
Registration date: **2023-01-17, 1401/10/27**
Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**
Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Hamidreza Javadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 2931

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Aspirin, Statin, Nitrate drug regimen on the quality of life in patients with Coronary slow flow disease and its comparison with the addition of Nicorandil

Public title
The effect of adding Nicorandil to the three-drug regimen on the quality of life in patients with Coronary slow blood flow disease
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to Bu-Ali Sina Referral Center who are candidates for coronary angiography based on clinical criteria, echocardiography, or other causes except for acute myocardial infarction or its history and complications (such as arrhythmias or conduction disorders), and then using The relevant criteria for diagnosing slow flow coronary syndrome are set for them.
Exclusion criteria:
Patients with a history of Myocardial infarction, Coronary artery bypass graft surgery, Percutaneous coronary intervention, Heart failure, Valvular heart disease, connective tissue disorders, Atrio-ventricular conduction disorders, Chronic obstructive pulmonary disease, Electrolyte disturbance, Chronic kidney disease, Anemia, and Systemic Hypertension are excluded from the study. After coronary angiography, patients with coronary slow flow due to secondary causes including Coronary artery ectasia, Coronary artery aneurysm, Coronary artery spasm, Air embolism during the procedure, and Congenital anomalies of coronary arteries are excluded from the study. Patients who do not agree to participate in the plan for any reason or decide to withdraw from the plan at any time.
Age
From **20 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are allocated to one of the two intervention groups using the random block sampling method. Random allocation software version 2 with a fixed size of 4 is used to generate randomized blocks. The principal investigator and the patients are unaware of the assigned treatment group
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 Qazvin University of Medical Sciences
Street address
Department of Cardiovascular Diseases, Bu Ali Sina hospital, Bu Ali Sina Street
City
Qazvin
Province
Qazvin
Postal code
3413786165
Approval date
2022-12-21, 1401/09/30
Ethics committee reference number
IR.QUMS.REC.1401.270

Health conditions studied

1

Description of health condition studied
Slow flow coronary disease
ICD-10 code
I20.8
ICD-10 code description
Other forms of angina pectoris

Primary outcomes

1

Description
Reduction of patients' symptoms
Timepoint
Before and after the end of the medication period
Method of measurement
Clinical signs and symptoms

Secondary outcomes

1

Description

Improving the patients quality of life

Timepoint

Before and after the end of the medication period

Method of measurement

McNew Quality of life Questionnaire

Intervention groups

1

Description

First arm: conventional three-drug regimen of aspirin 80 mg/day, statin 20 mg/day, and nitroglycerin 2.6 mg twice daily for 2 months.

Category

Rehabilitation

2

Description

Second arm: a conventional regimen of three drugs (Aspirin 80 mg/day, Statin 20 mg/day, and Nitroglycerin 2.6 mg twice daily) along with 10 mg of Merck's Adancor brand Nicorandil twice daily

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Hamidreza Javadi

Street address

Department of Cardiovascular Diseases, Bu Ali Sina Hospital, Bu Ali Sina St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Sayad Mehdi Mir Hashmei

Street address

Mavadat St., Shahid Beheshti Blvd., Research and Technology Vice-Chancellor of Qazvin University of Medical Sciences, Qazvin, Iran

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Email

researchdpt@qums.ac.ir

Web page address

https://vcr.qums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Hamidreza Javadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Demographic data and outcome of study can be shared

When the data will become available and for how long
In the end of study, 1402

To whom data/document is available
It is available for researchers

Under which criteria data/document could be used
For further research, with the approval of the University Ethics Committee

From where data/document is obtainable
Correspond with the researchers by e-mail 1- Dr. Hamidreza Javadi, Email: javadi.hr@gmail.com 2. Dr. Amir Javadi, Email: Javadi_a@yahoo.com

What processes are involved for a request to access data/document
One working week after correspondence

Comments