

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of drug therapy with percutaneous coronary intervention in the treatment of chronic stable angina

Protocol summary

Study aim

Determination of drug therapy with percutaneous coronary intervention in the treatment of chronic stable angina

Design

Two arm parallel groups, not blinded, stratified randomization by gender, design of 100 patients (50 patients in each group).

Settings and conduct

Farshchian Cardiovascular Hospital, Hamedan Records of patients with chronic stable angina include ECG, function class, echocardiography and angiographic information are collected. They are divided into two groups. Before the intervention, quality of life questionnaire and basic information are recorded. 6 months later, patients are visited and quality of life is assessed for clinical signs, emergency and hospitalization, FC, and ECG. Echocardiography is taken if there are clinical signs. These results are compared with the patient's initial results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. More than 70% stenosis in at least one coronary artery 2. EF more than 30% Exclusion criteria: 1. Resistant angina class IV 2. Treatment-resistant heart failure 3. Cardiogenic shock 4. Anatomy inappropriate for PCI 5. Chronic renal failure 6. Proximal LAD obstruction 7. Triple Vessel Disease 8. Diabetes, smoker

Intervention groups

Group 1: drug treatment of ischemic heart disease Group 2: PCI treatment + drug treatment of ischemic heart disease

Main outcome variables

1. Quality of life: in terms of the patient's clinical symptoms and based on the chronic angina checklist 2. Go to the emergency room 3. Number of hospitalizations 4. Function Class : Angina classification based on the New York Heart Association. 5. Ejection fraction: The amount of left ventricular blood is expelled with each

contraction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211129053210N1**

Registration date: **2021-12-19, 1400/09/28**

Registration timing: **prospective**

Last update: **2021-12-19, 1400/09/28**

Update count: **0**

Registration date

2021-12-19, 1400/09/28

Registrant information

Name

Mahsa Movahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 8078

Email address

mahsa.movahedi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of drug therapy with percutaneous coronary intervention in the treatment of chronic stable angina

Public title
Comparison of drug therapy with percutaneous coronary intervention

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
More than 70% stenosis in at least one coronary artery
EF more than 30%
Exclusion criteria:
Resistant angina class IV Treatment-resistant heart failure Cardiogenic shock Anatomy inappropriate for PCI
Chronic renal failure Proximal LAD obstruction triple vessel disease Diabetes, smoker

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
stratified randomization by gender: An equal number of men and women participate in each group. The samples will be determined by Permuted block randomization using the table of random numbers of Allocation Random software. In this 2-group trial, 2 blocks of 50, including 25 participants in the intervention group and 25 participants in the medical group are selected. Blocking and allocation sequencing for concealment will be done by the person not involved in the research.

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 Hamadan University of Medical

Sciences
Street address
Hamadan University of Medical Sciences ,Shahid Fahmideh St.
City
Hamadan
Province
Hamadan
Postal code
8176763746
Approval date
2021-11-27, 1400/09/06
Ethics committee reference number
IR.UMSHA.REC.1400.695

Health conditions studied

1

Description of health condition studied

Chronic Ischemic Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description

Quality of life: In terms of the patient's clinical symptoms and based on the chronic angina checklist

Timepoint

Measurement of quality of life at the beginning of the study and 6 months after the intervention

Method of measurement

Chronic angina checklist

Secondary outcomes

1

Description

Go to the emergency room based on the patient's statements

Timepoint

Evaluation of emergency department visit 6 months after the intervention

Method of measurement

Based on the patient's statements

2

Description

Number of hospitalizations based on hospitalization documents

Timepoint

Evaluation of the number of hospitalizations 6 months after the intervention

Method of measurement

Based on hospitalization documents

3

Description

Function Class: Angina classification based on the New York Heart Association

Timepoint

Evaluation of class function at the beginning of the study and 6 months after the intervention

Method of measurement

Based on the patient's statements and New York Heart Association

4

Description

Ejection fraction based on echocardiographic findings

Timepoint

Ejection fraction at the beginning of the study and 6 months after the intervention

Method of measurement

Based on the patient's echocardiographic evidence

Intervention groups

1

Description

Control group: Cardiac ischemia drugs

Category

Treatment - Drugs

2

Description

Intervention group: Cardiac ischemia drugs with percutaneous coronary intervention

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Cardiovascular Hospital

Full name of responsible person

Mohammad Mehdi Monajjem

Street address

Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6517839131

Phone

+98 81 3838 1740

Email

m.monajjem97@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

8176763746

Phone

+98 81 3838 0717

Email

fanavari@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mahsa Movahedi

Position

Student Research Committee, Hamadan University of Medical Sciences

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Unit 6, No. 405, Javadieh St.

City

Hamadan

Province

Hamadan

Postal code

8176763746

Phone

+98 81 3838 8078

Email

mahsa.movahedi@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Monajjem

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Unit 6, No. 405, Javadieh St.

City

Hamadan

Province

Hamadan

Postal code

8176763746

Phone

+98 81 3838 8078

Email

mahsa.movahedi@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Mahsa Movahedi

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Unit 6, No. 405, Javadieh St.

City

Hamadan

Province

Hamadan

Postal code

8176763746

Phone

+98 81 3838 8078

Email

mahsa.movahedi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Age, gender, ejection fraction, emergency department visit, number of hospitalizations, quality of life and function class . Can be shared after unidentified people.

When the data will become available and for how long

Access period starts from 2022

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Provide appropriate treatment to patients with chronic stable angina

From where data/document is obtainable

Dr.Mohammad Mahdi Monajjem Farshchian
Cardiovascular Hospital, Hamadan, Angiography Unit E-mail: m.monajjem97@gmail.com

What processes are involved for a request to access data/document

Full introduction with email and contact number.

Comments