

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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@ymail.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.

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**Province**

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**Postal code**

8176763746

**Phone**

+98 81 3838 8078

**Email**

mahsa.movahedi@ymail.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

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**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**