

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of cardiac rehabilitation on endothelial function and HbA1c in diabetic patients with Ischemic Heart disease

#### Protocol summary

##### Summary

Objective: To evaluate the effect of cardiac rehabilitation on endothelial function and HbA1c in patients with diabetes and ischemic heart disease. Study Design: Non-randomized study. Inclusion criteria; patients with type 2 diabetes have proved that diabetes treated with oral diabetes medications, PCI or CABG with recent history for rehabilitation are introduced. Exclusion criteria; patients who smoke and those who have been smoking during the past 5 years are excluded. Cardiovascular disorders and complications that require close care specialist such as severe ventricular arrhythmias and other serious complications. Intervention: Cardiac rehabilitation. Sample: A total of 53 intervention. Groups: One month after CABG, and two weeks after PCI. Primary outcome: Change in ABI and HbA1C. Secondary outcomes: Changes in GFR, FBS, lipid profile, BMI and METS. This study with a control group of 25 people, including the rehabilitation of diabetic patients with Ischemic Heart Disease is not done for them, all testing groups, including CBC, FBS, BUN, Cr, TG, CHOL, LDL, HDL and HbA1C in the control group and ABI asking twice, beginning and after two months out. And compared the results with the experimental group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015091924089N1**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-02, 1394/09/11

#### Registrant information

##### Name

Masoumeh Mohammadirad

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4352 9921

##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

#### Expected recruitment start date

2015-09-20, 1394/06/29

#### Expected recruitment end date

2015-11-20, 1394/08/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of cardiac rehabilitation on endothelial function and HbA1c in diabetic patients with Ischemic Heart disease

#### Public title

Effect of cardiac rehabilitation on vascular function and glycemic condition in diabetic patients with Ischemic Heart disease

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patients treated with oral

blood glucose lowering drugs, with history of CABG or PCI, they refer for Cardiac Rehabilitation Center of Imam Khomeini Hospital. Exclusion criteria: Smokers and those who have been smoking during the past 5 years are excluded: The reluctance of patients to participate in the study and not personal consent by the patient: Recurrent infarct during the study: Cardiovascular disorders and complications that require close care specialist such as severe ventricular arrhythmias and other serious complications: Treatment of diabetes with insulin:

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: 53

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****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 Ahvaz University of Medical Sciences

**Street address**

Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz

**City**

Ahvaz

**Postal code**

61357-15794

**Approval date**

2015-05-23, 1394/03/02

**Ethics committee reference number**

IR.AJUMS.REC.1394.89

**Health conditions studied****1****Description of health condition studied**

Ischemic Heart Disease

**ICD-10 code**

I20, I21,

**ICD-10 code description**

Ischaemic heart diseases

**Primary outcomes****1****Description**

Ankle Brachial Index

**Timepoint**

Before and after intervention

**Method of measurement**

By Vascular Screening Device VaSeraVS-1500N model

**2****Description**

HbA1C

**Timepoint**

Before and after intervention

**Method of measurement**

HbA1c blood and laboratory use

**Secondary outcomes****1****Description**

METS

**Timepoint**

Before and after study

**Method of measurement**

The Duke questionnaire

**2****Description**

Fasting Blood Sugar

**Timepoint**

Before and after study

**Method of measurement**

Blood Sample

**3****Description**

Blood Pressure

**Timepoint**

Before and after study

**Method of measurement**

By Manometer

**4****Description**

Glomerular filtration rate

**Timepoint**

Before and after study

**Method of measurement**

## 5

### Description

Body Mass Index

### Timepoint

Before and after study

### Method of measurement

The ratio of height to weight

## 6

### Description

Lipid Profil

### Timepoint

Before and after study

### Method of measurement

Blood Sample

## Intervention groups

### 1

#### Description

Intervention: cardiac rehabilitation, which includes a period of 1 hour exercise, including warm-up period of about 10 minutes, then 40 minutes of exercise with a treadmill, stationary bike or exercising arm (according to the protocol outlined monitoring each patient) and finally cooling period is for about 10 minutes. Cardiac monitoring is done during exercise. Total cardiac rehabilitation program is 24 sessions.

#### Category

Rehabilitation

### 2

#### Description

The control group included patients with a history of Cardiovascular disease who are treated with anti-ischemic drugs.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Cardiovascular Rehabilitation Center, Imam Khomeini Hospital, Azadegan Street, Ahvaz, Khoozestan Pro

##### Full name of responsible person

M. Mohammadi Rad Resident of Cardiology

##### Street address

Cardiovascular Rehabilitation Center, Imam Khomeini Hospital, Azadegan Street, Ahvaz, Khoozestan Province, Iran

##### City

Ramhormoz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research univercity of ahvaz

##### Full name of responsible person

Dr.Nader Saki

##### Street address

Vice chancellor for research, Ahvaz Univercity of Medical Science, Golestan Blvd, Ahvaz, Khoozestan Province, Iran

##### City

Ahvaz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research univercity of ahvaz

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Masoumeh Mohammadirad

##### Position

Assistant Professor of Cardiology

##### Other areas of specialty/work

##### Street address

No. 69, Zidane alley, Salman Farsi, Ramhormoz

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

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**Position**

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**Position**

Assistant Professor of Cardiology

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*