Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Masoumeh Mohammadirad
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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 Suger

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

Cockcroft-Gault Equation

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
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Masoumeh Mohammadirad
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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