

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of Hospital-Based Rehabilitation Versus Home-Based Exercise Training in Patients After Coronary Artery Bypass Grafting(CABG): Effects on Functional Capacity, Quality of Life, Psychological Symptoms, and Hemodynamic Parameters

Protocol summary

Summary

Main goal of our study is comparing hospital-based rehabilitation versus home-based exercise training in patients after CABG to compare whether they have differences in exercise tolerance test, echocardiographic indices and quality of life, by comparing maximum heart rate with rest time, changes in systolic and diastolic pressures, evaluate the 6-minute walk test score, ejection fraction (EF) , diastolic indicators to evaluate the performance of the ventricles, comparing the rate pressure product (RPP), quality of life and score of depression at end of rehabilitation program between both groups. Mentioned items assess in all 3 study groups. Patients who have history of CABG in previous 4 to 8 weeks and Stroke volume, more than 40 percent without history of unstable angina are eligible for our study. All patients give recommendation of receiving rehabilitation services in rehabilitation center of Tehran Heart Center. Those who accept the recommendations, will be in group 1, patient that could not receive rehabilitation services from Tehran Heart Center but accept take part in home-based program will be in group 2 and those not accept rehabilitation program will constitute in group 3(control group). At the end of 12 weeks rate of changes in mention indices will be measure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013132290N2**

Registration date: **2017-07-25, 1396/05/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

Ali Vasheghani Farahani

Name of organization / entity

Cardiologist Of Tehran Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6405 3481

Email address

medicalfrd@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of research, Tehran University of Medical Sciences

Expected recruitment start date

2017-07-11, 1396/04/20

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Hospital-Based Rehabilitation Versus Home-Based Exercise Training in Patients After Coronary Artery Bypass Grafting(CABG): Effects on Functional Capacity, Quality of Life, Psychological Symptoms, and

Public title

Cardiac Rehabilitation In Coronary Artery Bypass Grafting (CABG) Patients

Purpose

Supportive

Inclusion/Exclusion criteria

"Inclusion criteria": • stroke volume more than 40% • Coronary artery bypasses surgery recently in previous 4 to 8 weeks • Having a normal response to exercise test
"Exclusion criteria": • ventricular arrhythmias • atrial fibrillation • uncontrolled hypertension • type 2 diabetes • systemic disease and pulmonary that limited Sports • physical disabilities and any conditions limited Sports • severe valvular heart disease • known or suspected aortic dissection

Age

From **35 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

N/A

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 of Tehran University of Medical Sciences

Street address

Headquarters Building of Tehran University of Medical Sciences , Keshavarz "Blvd"

City

Tehran

Postal code

Approval date

2016-12-19, 1395/09/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1261

Health conditions studied

1

Description of health condition studied

Patient with Coronary Artery Bypass Grafting Surgery

ICD-10 code

121-122-12

ICD-10 code description

121-Acute myocardial infarction 122-Subsequent myocardial infarction 123-Certain current complications following acute myocardial infarction 125-Chronic ischaemic heart disease

Primary outcomes

1

Description

Score in Six minute walk test (MWT)

Timepoint

8 weeks after starting intervention

Method of measurement

Pedometr

2

Description

Rate Pressure Product

Timepoint

12 Weeks after starting intervention

Method of measurement

Exercise Test

3

Description

Ejecton Fraction (EF)

Timepoint

Based and 12 weeks later

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Quality Of Life

Timepoint

Base and 12 weeks later

Method of measurement

Questionnaire

2

Description

Tei index

Timepoint

12 weeks after intervention

Method of measurement

Echocardiography

3

Description

Depression

Timepoint

Base and 12 weeks later

Method of measurement

Questionnaire

4

Description

Systolic and Diastolic Blood Pressure

Timepoint

At base and 12 weeks after intervention

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Second group will receive rehabilitation at home, take exercise program after being discharged from hospital, advised to exercise orderly and call doctor when having a problem. In order to motivate this group they will receive periodic telephone calls. A pedometer device will give them to measure the amount of their activity objectively. An educated nurse will call them weekly and ask them about calorie intake and walking distance which measured by pedometer

Category

Rehabilitation

2

Description

The study included two intervention groups and one control group. The first intervention group received hospital-based usual rehabilitation program from rehabilitation center of Tehran Heart Center

Category

Rehabilitation

3

Description

The control group with the same schedule as group 2 will be followed up by phone. For Ethical principles, we will advise control group to received rehabilitation program from rehabilitation center of Tehran Heart Center or having regular physical activity at homes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Ali Vasheghani Farahani

Street address

Cardiac Rehabilitation center of Tehran Heart Center, North Kargar

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of research, Tehran University of Medical Sciences

Full name of responsible person

Masoud Yunesian

Street address

Floor 6, Official Building of Tehran University of Medical Sciences, Corner of Qods

City

Tehran

Grant name

Grant code / Reference number

95-01-30-30148

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

Yes

Title of funding source

Vice Chancellor of research, Tehran University of Medical Sciences

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

Tehran Heart Center

Full name of responsible person

Negar Omid

Position

Faculty Member of Cardiology Department

Other areas of specialty/work

Street address

Floor 2, Research Center Building, Tehran Heart Center, North Kargar "St"

City

Tehran

Postal code

Phone

+98 21 8802 9600

Fax
Email
negar.omidi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran Heart Center
Full name of responsible person
Negar Omid
Position
Cardiologist
Other areas of specialty/work
Street address
Floor 2, Research Center Building, Tehran Heart Center, North karegar
City
Tehran
Postal code
Phone
+98 912 225 6314
Fax
Email
negar.omidi@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran Heart Center
Full name of responsible person
Negar Omid
Position
Faculty Member of Cardiology Department
Other areas of specialty/work
Street address
Floor 2, Research Center Building, Tehran Heart Center, North Karegar
City
Tehran
Postal code
Phone
Fax
Email
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