Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

The comparison of the effect of two cardiac rehabilitation protocols (functional and ordinary) on atherosclerosis biomarkers and functional capacity in coronary arteries patients

Protocol summary

Study aim

The effect of 8 weeks of cardio functional training by ordinary cardiac rehabilitation protocol on cardiac injuries biomarker serum and functional indices in coronary artery patients.

Design

The current research is a semi-experimental type, which is conducted with two experimental groups in the form of a pre-and post-test. The population of the current study consists of patients with coronary artery disease. G.power software was used to select the statistical sample size with test power (1_β=0.95) and significance level (α=0.05) participating in the present study. Then the selected people are randomly divided into two control and rehabilitation exercise groups (functional and normal groups).

Settings and conduct

After meeting the entry criteria, the patients will be selected under the supervision of a specialist doctor at the Cardiovascular Research Institute of Isfahan University of Medical Sciences. After completing the consent form the selected people, their height, weight, and body composition will be measured. Then, functional tests including a 6MWT, TUG, Gait speed, blood pressure, and resting heart rate are performed. After taking the initial blood sample while fasting on the next day, the subjects are randomly assigned to two groups of functional training and normal training for 8 weeks, 3 sessions per week and each session is 45 minutes, and 72 hours after the last session Practice tests taken in the pre-test will be taken from them again.

Participants/Inclusion and exclusion criteria

Coronary artery patients who have a history of surgery use Beta blockers have a history of smoking, dyslipidemia, and hypertension, patients who are over 50 years old, participate in cardiac rehabilitation centers, have no use of alcohol, and do not have a history of regular exercise training.

Intervention groups

Ordinary and functional group

Main outcome variables

Apo-b, MPO, TUG, Gait speed, 6MWT.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231111060023N1**
Registration date: **2023-11-30, 1402/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-30, 1402/09/09**
Update count: **0**

Registration date

2023-11-30, 1402/09/09

Registrant information

Name

Arezoo Soleymani fard

Name of organization / entity

Allameh Tabataba'i University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of two cardiac rehabilitation protocols (functional and ordinary) on atherosclerosis biomarkers and functional capacity in coronary arteries patients

Public title

The comparison of cardiac rehabilitation protocols (functional and ordinary) on atherosclerosis biomarkers and functional capacity in coronary arteries patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Coronary artery patients who have surgery, usage of Beta blockers, patients who are over 50 years old, have hypertension, smoking, dyslipidemia, do not have a history of regular exercise, and participate in cardiac rehabilitation programs.

Exclusion criteria:

Usage of Alcohol. Disabled to do exercise, having a history of regular exercise training.

Age

From **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Research Ethics Committees of Allameh Tabataba'i University (ATU)

Street address

13th floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simai Iran St., between South Flamak and Zarafshan, Quds Town (West), Tehran

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Approval date

2023-06-01, 1402/03/11

Ethics committee reference number

IR.ATU.REC.1402.015

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Apo-B

Timepoint

24 hours before the intervention and 72 hours after the intervention.

Method of measurement

In order to measure the amount of apoB, 10 cc of blood is taken first. Then 3-4 cc of it will be frozen and then placed in a centrifuge. The samples will be kept at a temperature of 20 degrees and then frozen at a temperature of 70 degrees Celsius. Finally, they will be measured using the biomarker kit from the isolated plasma.

2

Description

MPO

Timepoint

24 hours before the intervention and 72 hours after the intervention.

Method of measurement

In order to measure the amount of MPO, 10 cc of blood is taken first. Then 3-4 cc of it will be frozen and then placed in a centrifuge. The samples will be kept at a temperature of 20 degrees and then frozen at a temperature of 70 degrees Celsius. Finally, they will be measured using the biomarker kit from the isolated plasma.

Secondary outcomes

1

Description

6MWT

Timepoint

24 hours before the intervention and 72 hours after the intervention.

Method of measurement

It is a simple and inexpensive test, well tolerated by the patient. Also, a walking test for 6 minutes is an alternative to a cardiopulmonary exercise test (CPET) for risk classification in heart failure patients. The walking test should be performed for 6 minutes, preferably inside a closed space, on a flat surface in a corridor with a hard surface, and on a straight path that is usually at least 30 meters long. The patient is told to keep calm, take his medication, and wear comfortable clothes and shoes. The observer records baseline oxygen saturation, heart rate, brachial arterial blood pressure, and Borg scale ratings for dyspnea and fatigue. Now the patient understands the relevant instructions and then prepares to start the test. The walking path must be marked every 3 meters. It is also recommended to place cones at the turns of the paths. During the test, the participants are required to walk at a suitable speed according to their conditions, and they are allowed to do so if they wish to do so. Slow down in the road and stop. Then continue walking as soon as possible. The supervisor should always be ready to provide encouragement to the patient with appropriate phrases such as "You are doing well" and "Keep doing what you are doing". Encouragement has been shown to affect distance traveled, especially in the pediatric population. At the end of the test, the observer again records the Borg scale for shortness of breath and fatigue, and then selectively measures arterial blood pressure, heart rate, and oxygen saturation. The number of laps and additional distance covered by the registration and test is calculated by 6 minutes of walking.

2

Description

TUG

Timepoint

24 hours before the intervention and 72 hours after the intervention.

Method of measurement

The test of getting up and walking is the ability to perform consecutive movement tasks compared to walking and returning. This test is for a distance of 3 meters in a standard way, so that in the first stage, the initial rest is done, then the movement of getting up from the chair, then walking the path to the distance is three meters, turning the track, sitting on a chair and finally taking a final rest. Also, this test has been used to predict the risk of falling at the global level and has been widely accepted as a standard protocol for measuring the basic functional mobility of patients with Parkinson's disease. The normal time to complete this test is 8-12 seconds, which depends on age, and the observations obtained from the get-up-and-go test provide valuable medical information about strength (getting up from a chair), mobility (walking a short distance), and It provides balance (rotation) at the same time in an efficient manner

3

Description

Gait Speed

Timepoint

24 hours before the intervention and 72 hours after the intervention.

Method of measurement

First, the person walks in a normal state (walking with the aid that is allowed) in a straight line on a flat surface from a starting point to a standing position at a distance of 9 meters. The first distance is 2/ 5 meters. There is no time for 2/5 meters (which is called the acceleration phase). The time taken to move to the next 4-meter track is recorded by a hand-held stopwatch, and then the patient has another 5.2-meter track to be in a stationary position (called the deceleration phase). The fastest two consecutive test phases are recorded. It is described in meters per second.

Intervention groups

1

Description

Functional group: Functional training group: In the functional training group, moderate functional training (MIFT) will be used, which will include performing functional movements in a circle and using the rule of maximum number and possible rounds (AMRAP) in a period of 30 minutes. The movements will include six major movements, which are: squat, step-up, lunge, high knee jog, rotation with pivot, and Butt-kick jog. During the whole 30 minutes, the heart rate of the subjects will be controlled, and like aerobic training, the intensity of these exercises will be 60% to 80% of the training capacity, using the reserve heart rate, resting heart rate in a stationary or sitting position (HRrest). 20 to 30 beats.min-1} { or the level of perception of pressure 16-12 will be controlled on the scale of 6-20.

Category

Treatment - Devices

2

Description

Ordinary group: Subjects will train for 8 weeks, 3 sessions a week and each session will last 45 minutes. All sessions include a standard 10-minute warm-up that includes stretching (eg, upper neck mobility, shoulders, thoracic spine, hips, and ankle mobility) and an activity. Cardiovascular and neuromuscular briefs will be without resistance. Next, light static and dynamic stretching will be done. The aerobic training part of each session is rhythmic with large muscle group activities with an

emphasis on increasing calorie consumption using a treadmill and bicycle. The duration of aerobic exercise will be 30 minutes and based on ACSM recommendations for people with cardiovascular disease characteristics participating in cardiac rehabilitation. The intensity of these exercises will be 60% to 80% of the training capacity, using the reserve heart rate, resting heart rate in a stationary or sitting position (HRrest)+20 to 30 beats.min-1} { or the pressure perception rate of 12-16 in the 6-20 scale will control. After completing the aerobic training part, the subjects will rest for 2 minutes. Finally, the training session will end with a 5-minute cooling down, including static and dynamic stretching movements, focusing on large joints.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan cardiovascular research institute

Full name of responsible person
Masoumeh Sadeghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Allameh Tabataba'i University

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Allameh Tabataba'i University

Proportion provided by this source
15

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
Allameh Tabataba'i University

Full name of responsible person
Rasoul Eslami

Position
Associate Professor

Latest degree
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Other areas of specialty/work
Exercise Physilogy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to the confidentiality of some patient information and their lack of consent to publish it.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available