Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of Cardiac Rehabilitation with usual care on Cardio_pulmonary function of patients with X syndrome

Protocol summary

Summary

The aim of the study is to compare the effect of cardiac rehabilitation plus medical treatment of patients suffering from coronary microvascular disease (X syndrome) with the same patients who are only under medical treatment. The study population are the patients with microvascular disease that have triad of angina pectoris, abnormal perfusion scan or exercise stress test and normal angiography (obstruction below 50%) with appropriate medical treatment. The subjects will be divided into two groups with randomized blocks. The intervention group will receive cardiac rehabilitation plus medical treatment and the control group will receive only medical treatment. There are 15 subjects in each group. Cardiac rehabilitation will be done for one month (3 sessions each week for total of 12 sessions). The main outcome is maximal aerobic capacity which is measured by cardio-pulmonary exercise test. Secondary outcomes are ventilatory threshold, Duck index, exercise duration, heart rate response and recovery. The researchers and the analysis committee will be blinded to the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101024401N2**
Registration date: **2016-06-26, 1395/04/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-06-26, 1395/04/06

Registrant information

Name

Reza Mazaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences.

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Cardiac Rehabilitation with usual care on Cardio_pulmonary function of patients with X syndrome

Public title

Comparing the effect of Cardiac Rehabilitation with usual care on Cardio_pulmonary function of patients with X syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients with angina pectoris; Abnormal perfusion scan; Normal angiogram with the coronary obstruction of below 50%; Receiving appropriate medical treatment. Typical or definite angina is sub-sternal chest discomfort that may radiate to the

back, jaw, or arms, and/or symptoms which provoked by exertion or emotional stress and relieved by rest or nitroglycerin. Exclusion criteria: Acute coronary syndromes; Uncontrolled hypertension (resting systolic blood pressure > 180 mm Hg and/or resting diastolic BP > 110); Significant aortic stenosis (aortic valve area < 1.0 cm2); Acute thrombophlebitis; Uncontrolled atrial or ventricular arrhythmias; Sinus tachycardia (>1 20 beats per minutes); Third-degree atrioventricular (AV) block without pacemaker; Acute pericarditis or myocarditis; Decompensated heart failure; Acute systemic illness or fever; Severe orthopedic conditions that would prohibit exercise; Other metabolic conditions such as acute thyroiditis, hypokalemia, hyperkalemia, or hypovolemia (until adequately treated).

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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, Tehran University of Medical Scinces

Street address
Keshavarz boulevard - Ghods street

City
Tehran

Postal code

Approval date
2015-11-22, 1394/09/01

Ethics committee reference number
IR.TUMS.REC.1394.1209

Health conditions studied

1

Description of health condition studied
Microvascular coronary syndrome

ICD-10 code
I20.9

ICD-10 code description
Anginal Syndrome

Primary outcomes

1

Description
Maximal aerobic capacity

Timepoint
One month

Method of measurement
cardio_pulmonary exercise test

2

Description
Duck Score

Timepoint
One month

Method of measurement
Exercise test

Secondary outcomes

1

Description
Ventilatory threshold

Timepoint
One month

Method of measurement
Cardio_pulmonary exercise test

2

Description
Duck questionaire

Timepoint
One month

Method of measurement
Cardio_pulmonary exercise test

3

Description
Recovery heart rate

Timepoint
One month

Method of measurement
Cardio_pulmonary exercise test

4

Description
Heart rate response

Timepoint

One month
Method of measurement
Cardio_pulmonary exercise test

5

Description
Exercise duration
Timepoint
One month
Method of measurement
Cardio_pulmonary exercise test

Intervention groups

1

Description
Control group: Routine medical treatment of cardiovascular risk factors including hyperlipidemia and hypertension.
Category
Treatment - Drugs

2

Description
Intervention: 12 sessions of cardiac rehabilitation including 3 sessions per week with intensity of 40-60% hear rate reserve or the BORG scale of 11-15 for each session up to 60 minutes and routine medical treatment of cardiovascular risk factors including hyperlipidemia and hypertension.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Sepideh Niyazi
Street address
End of Keshavarz boulevard-Imam khomeini hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Spideh Niyazi
Street address
End of Keshavarz Blv, Tehran, Iran
City
Tehran
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, 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 University of Medical Sciences
Full name of responsible person
Sepideh Niyazi
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Person responsible for scientific inquiries

Contact
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Web page address

Person responsible for updating data

Contact

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