

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effects of Exercise - Based Cardiac Rehabilitation on control of rhythm and Quality life in patients with chronic Atrial fibrillation

Protocol summary

Summary

This randomized Clinical study is going to be done in Tehran Heart Center. Patients with chronic atrial fibrillation with NYHA FC II or more who live in Tehran participate in this study. The patients do not have significant differences with each other in echocardiographic findings or past medical history. Patients who have contraindications for exercise are excluded. At first, candidate patients perform 12-ECG, echocardiography & exercise test. 50% of patients randomly divide into 2 groups (CR & control) according to Balanced Block Randomization method. The rest of the patients are divided according to the analysis of the results of different parameters. In CR group, patients participate in cardiac rehabilitation program for 1 month, but in control group, patients are not to be intervened except general advices for patients with cardiac disease. At the end of the study, the mentioned tests are done again for all of the patients. Rehabilitation protocol used for CR group in Heart Center consists of 12 sessions during 4 weeks (3 times each week). Each session includes of three 20-min period of warm-up, cardiac re-education and cool-down.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102315128N1**

Registration date: **2014-09-08, 1393/06/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-08, 1393/06/17

Registrant information

Name

Fatemeh Khodadadi

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

Phone

+98 21 8826 2745

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Exercise - Based Cardiac Rehabilitation on control of rhythm and Quality life in patients with chronic Atrial fibrillation

Public title

The effect of Cardiac Rehabilitation in making a better life for patients with Atrial Fibrillation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients with chronic atrial fibrillation ; with NYHA FC II or more; not having significant differences with other patients in past medical history and echocardiographic findings; patients who live in

Tehran. Exclusion criteria: Patients with chronic atrial fibrillation who have contraindications for exercise.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 140

Randomization (investigator's opinion)

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

Medical Ethics and History of Medicine Research
Center of Tehran University of Medical Sciences

Street address

No. 23,4th Floor, before Pour Sina St., 16th Azar St. ,
Keshavarz Blvd. Tehran Tehran Iran, Islamic Republic
Of

City

Tehran

Postal code

Approval date

2013-10-13, 1392/07/21

Ethics committee reference number

92-01-149-18944-95130

Health conditions studied

1

Description of health condition studied

atrial fibrillation

ICD-10 code

I48

ICD-10 code description

فیبریلاسیون و فلاتر دهلیزی

Primary outcomes

1

Description

number of heart rate

Timepoint

before intervention-after intervention

Method of measurement

number of heart rate in one minute

2

Description

Quality of life

Timepoint

before intervention-after intervention

Method of measurement

SF-36 Questionnaire

Secondary outcomes

1

Description

physical activity measure

Timepoint

before intervention-after intervention

Method of measurement

IOAQ questionnaire

2

Description

having depression or not

Timepoint

before intervention

Method of measurement

Beck test

Intervention groups

1

Description

Rehabilitation protocol used for CR group in Heart Center consists of 12 sessions during 4 weeks(3 times each week).Each session includes of three 20-min period of warm_up,cardiac re-education,and cool_down.

Category

Rehabilitation

2

Description

In control group,patients are not to be intervened except general advices for patiens with cardiac disease.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Fatemeh khodadadi

Street address

karegare shomali avenue, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shaahin akhoondzadeh

Street address

No 206, Flat 1, Building no 1, Medicine Faculty,
Poursina st., 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

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

Fatemeh khodadadi

Position

Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Tehran University of Medical Sciences

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Other areas of specialty/work

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Person responsible for updating data

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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