

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

A study of the effect of aerobic physical rehabilitation on the quality of life of patients with chronic atrial fibrillation hospitalized in the cardiac care unit

Protocol summary

Summary

Research objective: to determine the effect of aerobic physical rehabilitation on the quality of life of patients with chronic atrial fibrillation hospitalized in the cardiac care unit Design: the present research is a clinical trial study that was conducted on 50 patients with chronic atrial fibrillation hospitalized in the cardiac care unit. Inclusion criteria were including: Stable physical status; not having known psychiatric disorder or physical-mental disability; Not having history of chronic heart failure, and exclusion criteria were including: Treatment-resistant hypertension; Having atrial fibrillation with fast ventricular response; sampling method was simple and the research was blind and one-way study. The participants were randomly divided into two experimental (25 participants) and control (25 participants) groups.) Intervention, In the experimental group: the subjects of experimental group were asked to do according to a rehabilitation program in the form of a training package and aerobic scheduled physical activities and aerobic activities (such as walking, jogging and aerobics) for 8 weeks (2 sessions per week) with light and moderate intensity according to the opinion of the cardiologist. In the control group, other interventions, the routine program of intensive care unit and three sessions of the group training course were held at the beginning, 4 weeks and 8 weeks after the intervention. By the use of quality of life questionnaire (SF_36) before and after the end of intervention, the quality of life of the both groups was assessed by questioning. The data collected were analyzed statistically by SPSS V.20 software. main outcome measures : quality of life Secondary output: blood pressure and ejection fraction

General information

Acronym

Quality of life in patients with atrial fibrillation (QOL IN AF)

IRCT registration information

IRCT registration number: **IRCT2016122727073N2**

Registration date: **2017-11-20, 1396/08/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Asghar Khalifehzadeh Esfahani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Isfahan University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A study of the effect of aerobic physical rehabilitation on the quality of life of patients with chronic atrial fibrillation hospitalized in the cardiac care unit

Public title
The effect of aerobic physical rehabilitation on the quality of life of patients with atrial fibrillation

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Stable physical status; not having known psychiatric disorder or physical-mental disability; Not having history of chronic heart failure, dementia, disability or contraindication for exercise; Not having atrial fibrillation with fast ventricular response; Having heart rate below 100; Not being pregnant or breastfeeding, the patient receives anti-coagulant
Exclusion criteria: Treatment-resistant hypertension; Having atrial fibrillation with fast ventricular response; having heart rate greater than 100 during performing physical rehabilitation program; Re-admission after discharge in the past month; Atrial fibrillation patients with Pacemaker or functional impairment (according to the specialist's diagnosis), ICD and coagulation disorders.

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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 of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjaryb St,
Isfahan

City
Isfahan

Postal code
8174673461

Approval date
2016-10-15, 1395/07/24

Ethics committee reference number
IR.Mui.Rec.1395.3.538

Health conditions studied

1

Description of health condition studied

فیبریلاسیون دهلیزی

ICD-10 code

148

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes

1

Description

Quality of life

Timepoint

pre intervention and post intervention

Method of measurement

Quality of life SF36 questioner

Secondary outcomes

1

Description

EjectionFraction

Timepoint

Before and after intervention

Method of measurement

Echocardiogram

2

Description

blood pressure

Timepoint

Per session

Method of measurement

manometer

Intervention groups

1

Description

For the control group, the routine care program was implemented that describes physical rehabilitation as verbal conversation and is more often the response to

the patient's questions about the educational and training pamphlet. During this, they did not participate in any organized sports program. For this group, three sessions of training were held at the beginning of the course, the fourth week and the eighth week.

Category

Rehabilitation

2

Description

In the experimental group: the subjects of experimental group were asked to do according to a rehabilitation program in the form of a training package and aerobic scheduled physical activities and aerobic activities (such as walking, jogging and aerobics) for 8 weeks (2 sessions per week) with light and moderate intensity according to the opinion of the cardiologist. Each session had 10 minutes warm up, 40 minutes of major movements and 10 minutes of relaxation and cooling. This aerobic physical rehabilitation program was conducted for patients in groups of 5 to 7 people.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Mohammad Montazeri Hospital in Najaf Abad

Full name of responsible person

Dr. Mehdi Eftekhari

Street address

Mohammad Montazeri Hospital, 17 Shahrivar St, Najaf Abad, Isfahan, Iran

City

Najaf Abad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan Medical Science University

Full name of responsible person

Deputy of Research of Isfahan University of Medical Sciences

Street address

Isfahan Medical Science University, Hezarjarib St, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan Medical Science University

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

Isfahan University of Medical Sciences

Full name of responsible person

Asghar Khalifehzadeh Esfahani

Position

Master of Science (Nursing)

Other areas of specialty/work

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Position

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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