

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 31 3567 7097

###### Email address

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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 questionnaire

## 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****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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## Person responsible for updating data

### Contact

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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*