

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluating the effects of self management interventions on life style and complications in patients with Atrial Fibrillation

Protocol summary

Summary

Main aim: Evaluating the effects of self management interventions on life style and complications in patients with Atrial Fibrillation. Inclusion criteria: All patients should be with chronic AF on the following basis: Sustained AF being treated with long-term pharmacological therapy with the intention of establishing optimal ventricular rate control and/or minimization of thrombotic risk, Recurrent paroxysmal or sustained AF being treated with pharmacological or electrical cardio-version with long-term pharmacotherapy to prevent recurrent AF and/or minimize thrombotic risk, Recurrent paroxysmal AF being treated with long term pharmacological therapy to minimize thrombotic risk; All patients should be more than 18; should not participate in any other study simultaneously; should be eager to participate in study and fill informed consent. Exclusion Criteria: Patients with C.V.A, cancer and liver failure; absence for more than two Sessions; suffering from psychological problems; not participating in study for any reason. Method: randomized controlled trial. Study population: all patients with atrial fibrillation in Fasa. Sample size:72 cases. Intervention: patients in intervention group will receive teaching in six sessions during three week period. Then we will call the patients fore three times (after the fourth, eighth, and twelfth week of intervention). Walker questionnaire and check lists will be completed for all cases in three times: before intervention, four weeks after intervention and twelve weeks after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082023606N3**

Registration date: **2015-11-10, 1394/08/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-10, 1394/08/19

Registrant information

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-06-20, 1394/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of self management interventions on life style and complications in patients with Atrial Fibrillation

Public title

The effects of self management interventions on life style and complications in patients with Atrial Fibrillation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Sustained AF being treated with long-term pharmacological therapy with the intention of establishing optimal ventricular rate control and/or minimization of thrombotic risk; Recurrent paroxysmal or sustained AF being treated with pharmacological or electrical cardio-version with long-term pharmacotherapy to prevent recurrent AF and/or minimize thrombotic risk; Recurrent paroxysmal AF being treated with long term pharmacological therapy to minimize thrombotic risk; All patients should be more than 18; should not participate in any other study simultaneously; should be able to comprehend Persian and communicate; should be eager to participate in study and fill informed consent.

Exclusion Criteria: Patients with C.V.A, cancer and liver failure; absence for more than two Sessions; suffering from psychological problems; not participating in study for any reason.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

7th floor, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Postal code

1978-71345

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

ct-9377-7347

Health conditions studied

1

Description of health condition studied

Atrial Fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial Fibrillation and flutter

Primary outcomes

1

Description

Life style

Timepoint

before education, four weeks after education, at the end of twelfth week

Method of measurement

Walker Questionnaire

Secondary outcomes

1

Description

Atrial Fibrillation Complications

Timepoint

before education, four weeks and twelve weeks after education

Method of measurement

Check list

Intervention groups

1

Description

Patients in intervention group will receive education in six sessions during three weeks and telephone follows up after fourth week, eighth week and twelfth week of intervention.

Category

Lifestyle

2

Description

control group will receive usual care.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Fasa Vali-e-Asr Hospital

Full name of responsible person

Hojat-o-Ilah Najafi

Street address

Vali-e-Asr Hospital, Avesena sq., Shahid Rajayi blvd.,
Fasa, Fars, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellery for research affairs

Full name of responsible person

Dr. Gholamreza Haatam

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7th floor, Shiraz University of Medical Sciences, Zand
Blvd., Shiraz, Iran

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellery for research affairs

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

Shiraz Medical University

Full name of responsible person

Mahnaz Rakhshan

Position

Ph.D.n

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Hojat-o-Ilah Najafi

Position

B.A

Other areas of specialty/work

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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