

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Assessing the effect of nursing care plan according “one care program “on Quality Of Life(QOL) in patients with Atrial Fibrillation(AF) Hospitalized to the Coronary Care Unit(CCU)

Protocol summary

Study aim

Determine the effect of a care plan on the quality of life of the patients with atrial fibrillation

Design

This is a randomized two-group clinical trial that was conducted on 50 patients diagnosed with atrial fibrillation and hospitalized in Coronary Care Unit(CCU). Fifty patients were selected through convenient sampling and were randomly assigned to intervention (n=25) and control (n=25) groups. a code was allocated to each one of them.

Settings and conduct

This is randomized two-group two- step clinical trial , conducted on 50 patients with atrial fibrillation hospitalized in Coronary Care Unit of Nour hospital , affiliated to Isfahan University of Medical Sciences, Iran . For the intervention group, a planned care program was performed and performed routine care for the control group. Quality of life was measured using a SF36 quality of life questionnaire before and one month after the end of the intervention.

Participants/Inclusion and exclusion criteria

Conditions for entering the research:patients with diagnosed atrial fibrillation hospitalized in CCU of Nour hospital , affiliated to Isfahan University of Medical Sciences, Iran. The patient's willingness to participate in the research project. Exclusion Consciousness of the Subjects Having Pacemaker and Implantable cardioversion Defibrillation No patients who live in Isfahan Unwillingness of the Patient to Continue to Participate in the Research Project life Threatening Physical Condition and Acute Psychotic Disorders.

Intervention groups

Control group : Control group underwent routine care including routine control of cardiac rate and rhythm , and prevention of thromboemboli , mostly administrated through oral and non-identical instructions ,and often,

with educational pamphlets by the nurses in the ward . Intervention group : In study group, a care plan was designed based on previous studies , forcing the nurses to administrate care according to a checklist including control of cardiac rhythm and rate , prevention of thromboemboli and atrial fibrillation and their treatment strategies, complications and educational program. Researcher precisely checked administration of the checklist by nurses.

Main outcome variables

The dependent variable was the quality of life and its dimensions, which was measured. 'quality of life(QOL) and domains of physical function, physical role, emotional role, happiness, mental health , social function, pain ,and general health.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160316027073N3**

Registration date: **2018-03-02, 1396/12/11**

Registration timing: **retrospective**

Last update: **2018-03-02, 1396/12/11**

Update count: **0**

Registration date

2018-03-02, 1396/12/11

Registrant information

Name

Asghar Khalifehzadeh Esfahani

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date
2015-06-10, 1394/03/20

Expected recruitment end date
2015-09-23, 1394/07/01

Actual recruitment start date
2015-06-10, 1394/03/20

Actual recruitment end date
2015-09-23, 1394/07/01

Trial completion date
empty

Scientific title
Assessing the effect of nursing care plan according "one care program "on Quality Of Life(QOL) in patients with Atrial Fibrillation(AF) Hospitalized to the Coronary Care Unit(CCU)

Public title
Effect of Nursing Care Program on Quality Of Life in patients with Atrial Fibrillation

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
patients with diagnosed atrial fibrillation hospitalized in CCU of Nour hospital , affiliated to Isfahan University of Medical Sciences, Iran . The patient's willingness to participate in the research project.
Exclusion criteria:
Consciousness of the Subjects Having Pacemaker and Implantable cardioversion Defibrillation No patients who live in Isfahan Unwillingness of the Patient to Continue to Participate in the Research Project life Threatening Physical Condition and Acute Psychotic Disorders

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The research units with inclusion criteria were entered into the study by simple sampling method and were randomly assigned to two groups of test and control using the random numbers table.

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 Isfahan University of Medical Sciences

Street address

Isfahan, Shiraz gate, 1000 Jreib Street, Isfahan University of Medical Sciences

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Isfahan

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Postal code

8174673461

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

IR.Mui.Rec.1394.3.270 شماره مجوز

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

quality of life

Timepoint

pre intervention and after one month post intervention

Method of measurement

Quality of life SF36 questionnaire

Secondary outcomes

1

Description

Ejection Fraction

Timepoint

before and one month after study

Method of measurement

Echocardiogram

Intervention groups

1

Description

In study group, a care plan was designed based on previous studies, forcing the nurses to administrate care according to a checklist including control of cardiac rhythm and rate, prevention of Thromboembolism and atrial fibrillation and their treatment strategies, complications and educational program. Care plan also contained medical cardioversion. checklist and heparin and warfarin thromboembolism prevention checklist.

Category

Rehabilitation

2

Description

Control group: Firstly, demographic characteristics and QOL questionnaires were completed by the researcher for all the subjects in both groups. Control group underwent routine care including routine control of cardiac rate and rhythm, and prevention of thromboembolism, mostly administrated through oral and non-identical instructions, and often, with educational pamphlets by the nurses in the ward.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

CCU of Nour hospital, affiliated to Isfahan University of Medical Sciences, Iran

Full name of responsible person

Dr. Jafar Golshahi

Street address

Ostandary Ave, Nour Hospital, Isfahan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Research Deputy for Isfahan University of Medical Sciences

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Isfahan, Shiraz gate, 1000 Jirib Street, Isfahan University of Medical Sciences, Building No. 4, Head of Department, Research and Technological D

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Web page address

http://research.mui.ac.ir

Grant name

Isfahan Medical Science University

Grant code / Reference number

دانشگاه علوم پزشکی اصفهان

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Asghar khalifehzadeh Esfahani

Position

Lecturer department of Critical nursing, Faculty of Nursing and Midwifery, Isfahan University of M

Latest degree

Master

Other areas of specialty/work

Nursery

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Disagreement with the research sponsor until the paper is submitted

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available