

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of telephone follow-up methods and group session on quality of life of patients with pacemaker in clinic Investment, Chamran Hospital in Isfahan

Protocol summary

Summary

The purpose of this study was to assess the effect of telephone follow up and group session on different domain of quality of life in patient with pacemaker. The inclusion criterias were the age between 18-85 and the first time implanaton and the exclusion criteria was Lack of consent to continue participating in the study. This was a prospective quasi experimental study that covered 60 patient divided into three groups. For 20 patient in intervention group 4 group session were performed one day a week, each session would last 20-40 min. For 20 patient in telephone follow up 12 phone calling were performed for 4 weeks, each call would last 20 min, control group received the routine intervention as a educational material. The data were collected through "AQOL" for physical status and the quality of life questionaries. Physical status and quality of life were evaluated after one month intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805132289N1**
Registration date: **2011-06-25, 1390/04/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-25, 1390/04/04

Registrant information

Name

Fateme Aliakbari

Name of organization / entity

Nursing Midwifery School

Country

Iran (Islamic Republic of)

Phone

+98 38 1334 4912

Email address

aliakbari@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2007-07-25, 1386/05/03

Expected recruitment end date

2008-02-28, 1386/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of telephone follow-up methods and group session on quality of life of patients with pacemaker in clinic Investment, Chamran Hospital in Isfahan

Public title

Effect of telephone follow-up methods and group session on quality of life of patients with pacemaker in clinic Investment ,Chamran Hospital in Isfahan

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients are aged 18-80 years; are of both sexes; complete the individual consciousness, awareness of time, place and person possible Drmtalh companies have; For the first time pacemaker is embedded; Patients who have the ability to participate in

the meetings are; have a telephone at home; mental disorder is not known in this field do not use drugs; speech and hearing problems are not known; during pregnancy and lactation not; surgery, while there is no pacemaker fitted; or physical mental disability which prevents the ability not participate in session. Exclusion criteria: patient's unwillingness to continue participating in the study

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Aliakbari

Secondary trial Id

386352

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Science

Street address

Hezarjrib street, Midwifery Dept, Nursing and Midwifery Faculty, Univ of Medical Science, Isfahan, Iran.

City

Isfahan

Postal code

Approval date

2007-09-23, 1386/07/01

Ethics committee reference number

386352

Health conditions studied

1

Description of health condition studied

Pacemaker Implatation

ICD-10 code

Y83.1

ICD-10 code description

Surgical operation with implant of artificial internal device

Primary outcomes

1

Description

Quality of life

Timepoint

One month

Method of measurement

SF-36 questionaries

Secondary outcomes

1

Description

Physical condition

Timepoint

one month

Method of measurement

AQOL questionaries

Intervention groups

1

Description

For 20 patient in telephone follow up 12 phone calling were performed for 4 weeks, each call would last 20 min.

Category

Other

2

Description

For 20 patient in group session group 4 group session were performed one day a week, each session would last 20-40 min.

Category

Other

3

Description

For 20 patient in control group the routine intervention(giving educational material) was done.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital, Pace implatation clinic

Full name of responsible person

Street address

Salman-e Farsi street, Pace implatation clinic,
Chamran Hospital, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Research Assistant

Street address

Hezarjrib street, Research Assistant, Univ of Medical
Science, Isfahan, Iran.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Science

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Peyman Adibi

Street address

Hezarjrib street, Research Assistant, Univ of Medical
Science, Isfahan, Iran.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Science

Proportion provided by this source

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 Science

Full name of responsible person

Aliakbari Fateme

Position

Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Faculty member

Full name of responsible person

Khalifezade Asghar

Position

Instructor

Other areas of specialty/work

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Medical of Science

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Khalifezade Asghar

Position

Faculty member

Other areas of specialty/work**Street address**

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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