

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of self care Education on Quality of life among patients with permanent pacemaker

Protocol summary

Summary

Effect of Self-Care Education on Quality of life among Patients with Permanent Pacemakers at Rajaie Cardiovascular, Medical and Research Center in 2012
Inclusion criteria: All patients who are candidate for permanent pacemaker implantation :Exclusion criteria Patients with known psychiatric disorders; Patients with chronic diseases (epilepsy, stroke, cancer, ...); Patients with known physical disabilities (deaf, blind); History of major surgery (heart, brain, hip,...); Prolonged hospitalization; No consent for the study; Pacemaker implantation in other centers; Mental disorders; Patients who experience complications during procedure; Age less than 16 years; Patients who have no access to audiovisual devices to watch the educational movie
Patients in need for permanent pacemaker implantation are randomly assigned into two intervention group (n=40) and control group (n=40). Only patients in the intervention group are received self-care education by movie and pamphlet. Quality of life questionnaire for cardiac patients (Macnew) and self care questionnaire (designed by the study investigators) are completed for all patients before study and one month after device implantation. All data are analyzed by SPSS

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302211965N6**
Registration date: **2013-05-11, 1392/02/21**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-11, 1392/02/21

Registrant information

Name

Majid Haghjoo

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2163

Email address

majid.haghjoo@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self care Education on Quality of life among patients with permanent pacemaker

Public title

Self care Education and quality of life among patients with permanent pacemaker.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: All patients who are candidate for permanent pacemaker implantation
Exclusion criteria: Patients with known psychiatric disorders; Patients with chronic diseases (epilepsy, stroke, cancer, ...); Patients

with known physical disabilities (deaf, blind); History of major surgery (heart, brain, hip,...); Prolonged hospitalization; No consent for the study; Pacemaker implantation in other centers; Mental disorders; Patients who experience complications during procedure; Age less than 16 years; Patients who have no access to audiovisual devices to watch the educational movie

Age

From **16 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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, Tehran university of medical sciences

Street address

Tehran university of medical sciences

City

Tehran

Postal code

Approval date

2013-02-18, 1391/11/30

Ethics committee reference number

118546

Health conditions studied

1

Description of health condition studied

Arrhythmia

ICD-10 code

I30-I52

ICD-10 code description

Other forms of heart disease

Primary outcomes

1

Description

Quality of life

Timepoint

before intervention and 1 month after intervention

Method of measurement

MACNEW HEART DISEASE HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE

Secondary outcomes

empty

Intervention groups

1

Description

Patients in need for permanent pacemaker implantation are randomly assigned into two intervention group and control group. Only patients in the intervention group are received self-care education by movie and pamphlet about the heart function, pacemaker function, and pre- and postoperative care. Quality of life questionnaire for cardiac patients (Macnew) and self care questionnaire (designed by the study investigators) are completed for all patients before study and one month after device implantation.

Category

Other

2

Description

nothing intervention do in control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular medical and research center, tehran university of medical sciences, Tehran, Ir

Full name of responsible person

Dr. majid haghjoo

Street address

valiaser st, niayesh highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences
Full name of responsible person
 Dr. majid haghjoo
Street address
 valiaser st, niayaesh highway
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tehran University of Medical Sciences
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
 Rajaie Cardiovascular Medical and Research Center,
 Tehran university of medical sciences, Tehran, Ir
Full name of responsible person
 Dr. Majid Haghjoo
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Person responsible for scientific inquiries

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Name of organization / entity
 Rajaie Cardiovascular medical and research center,
 tehran university of medical sciences, Tehran, Ir

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Person responsible for updating data

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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