Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Position

Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Associated professor

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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