Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative effect of a cardiac rehabilitation program on adjustment; body Image and complication of patient with cardiac managment rhythm device.

Protocol summary

Summary

objectives: The aim of this study is comparison of a cardiac rehabilitation program on adjustment; body image and complication of patient with cardiac management rhythm device, Including permanent pacemaker(PM), cardiac resynchronization therapy devices (CRT) and implantable cardioverter defibrillator(ICD) at pace implantation clinic faqihi and ghalb zahra shiraze hospital sep 2014-sep 2015. Design: This study is a randomised clinical trial with control group. Setting and conduct: 100 patient with cardiac management rhythm device will be enrolled the survey. Patients will be divided into two groups randomly intervention(n=50) and control groups(n=50). Participants including major eligibility criteria: The major inclusion criteria is patients are age 18- 70 years and the first time implantation . The exclusion criteria are Lack of consent to continue participating in the study. Intervention: cardiac rehabilitation are used for the intervention group for a period of 2 months (24 Session). Control group receive routine medical care program. . Main outcome: The primery outcome are evaluation of complication (researcher- made questionnaire) , adjustment (psychosocial adjustment to illness questionnaire) and body Image (body image questionnaire). Before, 8 and 12 week after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014083118982N1**
Registration date: **2015-08-05, 1394/05/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-05, 1394/05/14

Registrant information

Name

Leila Ansarifard

Name of organization / entity

Square, Namazi, Shool of Nursing and midwifery

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2014-08-25, 1393/06/03

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of a cardiac rehabilitation program on adjustment; body Image and complication of patient with cardiac managment rhythm device.

Public title

Cardiac Managment Rhythm Devic

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients are aged 18-70 years; are of both sex; For the first time device is implanted; Patients who have the ability to participate in the rehabilitation program; speech and hearing problems are not known ; 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 **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patient occording number randomly table divided to intervention and controlls group.

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of'' Shiraz University of Medical Sciences"

Street address

Zand, Street, Central Building Of

City

Shiraze

Postal code

71345,1978

Approval date

2014-08-24, 1393/06/02

Ethics committee reference number

CT7128,93

Health conditions studied

1

Description of health condition studied

pacemaker implantation

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Adjustment

Timepoint

Befor, 8 Week and 12 Week After Intervention

Method of measurement

Psycho-Social Adjustment Scale(PIAS))

2

Description

Bodyimage

Timepoint

Befor,8 Week and 12 Week After Intervention

Method of measurement

Bodyimage And Relationsheep Questionnaire

3

Description

Complication

Timepoint

Befor, 8 Week And 12 Week After Intervention

Method of measurement

Researcher Made Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For Pacemaker patient in experimental group(25), the Cardiac Rehadilitation Program(CR) consisted of a 3 sessions(8 Weeks, every tow weeks,100 min)including exercise training 40 min, education 30 min and psycho-educational intervention30 min.

Category

Rehabilitation

2

Description

For implantable cardioverter defibrillator and synchronized bivantriculare pacing patient in experimental group(25), the Cardiac Rehadilitation Program(CR) consisted of a 3 Sessions(8 Weeks, every tow weeks,100 min) including exercise training 40 min, education 30 min and psycho-educational intervention30 min.

Category

Treatment - Drugs

3

Description

For (50) patient in contorl group the routine intervention was done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghalb Zahra Hospital

Full name of responsible person

leila Ansarifard

Street address

Qaeem Hospital

City

Firoozabad

2

Recruitment center

Name of recruitment center

Faqihi Hospital (Pacemaker Clinic)

Full name of responsible person

leila Ansarifard

Street address

Qaeem Hospital

City

Firoozabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellore for research, Shiraze university of Midical Scienes

Full name of responsible person

Dr.Seed,Baser Hashemi

Street address

Zand,Street,Shiraze University of Medical Sciences Center"

City

Shiraz University of Medical Sciences

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellore for research, Shiraze university of Midical Scienes

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

School of Nursing and Midwifery, Namazi, Square

Full name of responsible person

Dr.Mahnaz Rakhshan

Position

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Person responsible for scientific inquiries

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Full name of responsible person

Dr.Mahnaz Rakhshan

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Assistant Professar

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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