Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The clinical trial of the effects of education based on Orem self care model on the International Normalized Ratio(INR) and quality of life of patients with prosthetic heart valve

Protocol summary

Summary

The aim of this clinical trial is to determine the effect of education based on Orem Self Care Model on quality of life and control of international normalized ratio (INR) in patients with prosthetic heart valves.The study population includes all patients with prosthetic heart valves that are treated with warfarin referred to Warfarin Clinic of Al-zahra Heart Hospital. The study sample (94) will be selected by convenience sampling method and then is divided into control and experimental groups by the random block.Include criteria includes use of warfarin for at least three months and irregularly referring to warfarin clinic. Exclusion criteria includes planning to get pregnant and lack of follow-up of the treatment on a regular basis..Patients in the experimental group are identified based on Orem's needs assessment questionnaire.The intervention includes self-care education for 8 hours on an individual basis that will design according to the needs of patients in the Orem supportive-educational system. The program will be consists of three face to face training sessions for each person and four telephone sessions. Control group receives no intervension. Data will be collected by "Mac New heart patients Quality of life questionnair " and "test results record form". INR tests of both groups of patients will be done before, one and two months after the intervention, and the findings will be recorded. Also, all participants will complete quality of life questionnair before and two months after the intervention .The expected impact of INR control is in the normal range and quality of life in the intervention group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082829566N1**

Registration date: **2016-11-14, 1395/08/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name

Zeinab Mirzaei

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 5373 0201

Email address

elahi-m@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-11-05, 1395/08/15

Expected recruitment end date

2017-02-03, 1395/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The clinical trial of the effects of education based on Orem self care model on the International Normalized

Ratio(INR) and quality of life of patients with prosthetic heart valve

Public title
The effects of education based on Orem self care model on the International Normalized Ratio(INR) and quality of life of patients with prosthetic heart valve
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:Have willingness to participate in the study;Take warfarin for at least three months ; Regular warfarin clinic visit or be in contact by phone; Have the ability to read and write; Age between 18 and 60 years old. Exclusion criteria:Have decided to get pregnant ;Lack of follow-up of the treatment on a regular basis.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **94**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization is based on random blocks. So 23 blocks of 4 and one binary block is formed. Then the sequence of the blocks are randomly determined . The samples size will be equal in both groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Central Building Shiraz University of Medical Sciences;Zand Ave ;Shiraz.
City
Shiraz
Postal code
Approval date
2016-09-07, 1395/06/17
Ethics committee reference number
ir.sums.rec.1395.68

Health conditions studied

1

Description of health condition studied
Prosthetic Heart Valve
ICD-10 code
Z95.2
ICD-10 code description
Presence of prosthetic heart valve

Primary outcomes

1

Description
INR
Timepoint
Once a month
Method of measurement
INR tests

2

Description
Quality Of Life
Timepoint
The beginning and end of the study
Method of measurement
MacNew Quality of Life Questionnaire for cardiac patients

Secondary outcomes

empty

Intervention groups

1

Description
Group test: a self-care educational program held for 8 hours.This program is individually designed according to the needs of patients in the Orem supportive-educational system . Three face to face sessions training and four telephone sessions will be done for each person .
Category
Prevention

2

Description
Control group: In this group will not be any intervention.
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Warfarin Clinic Heart Hospital Zahra

Full name of responsible person
Zeinab Mirzaei

Street address
Al zahra hospital; Sibuyeh Boul; Shiraz; Iran

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Zeinab Mirzaei

Street address
Shiraz University of Medical Sciences;Zand Ave;Shiraz;Iran

City
Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Zeinab Mirzaei

Position
Nursing Graduate Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dr.Zahra Khademian

Position
Phd

Other areas of specialty/work

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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