

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 intervention. Data will be collected by "Mac New heart patients Quality of life questionnaire" 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 questionnaire 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

Name of organization / entity

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Dr.Zahra Khademian

Position

Phd

Other areas of specialty/work

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Other areas of specialty/work

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Shiraz; Student Blvd., Shiraz University, dormitory logo 6

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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