

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison the effect of two types short message service (interactive and non interactive) on adherence of patients with prosthetic heart valves

Protocol summary

Summary

The purpose of this study is comparison the effect of two types of short message service (interactive and non-interactive) on adherence of patients with prosthetic heart valves, with emphasis on the use of anticoagulant. This is a clinical trial study. The study population are patients with prosthetic heart valves, who refer to Imam Khomeini hospital of Tehran city. Ninety eligible patients are enrolled the study and randomly divide into three groups. Self-report questionnaire is completed with patients and their International Normalized Ratio (INR) levels are recorded. The researcher gives educational leaflets to all of the patients and takes their phone number and tells them how to use the short message service. To ensure sending the messages, the researcher activated the switch "delivered" on her phone. In illiterate patients, one of their family members is requested to check the messages. For The control group does not send any message. For non-interactive group, during three months every week four educational messages are sent. Each text message is maximum 160 characters. For interactive group, in addition sending educational message, patients have two way communications with the researcher by asking their questions. During three months, each patient has at least six interactions with the researcher. After three months, all three groups again complete the Self-report questionnaire. Adherence is evaluated with questionnaire and INR levels.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102011177N1**

Registration date: **2013-06-07, 1392/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-07, 1392/03/17

Registrant information

Name

Ahmad Ali Asadi Noughabi

Name of organization / entity

Nursing and Midwifery of Tehran University Medical of Science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-01-23, 1391/11/04

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two types short message service (interactive and non interactive) on adherence of patients with prosthetic heart valves

Public title

Education with short message service and adherence

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients who have prosthetic heart valves and their surgery are at least two months ago. Patients who take warfarin at least three months after surgery and their International Normalized Ratio (INR) must continuously be controlled. Patients who have at least literate to read and write. Patients who have a mobile phone at their home. Patients who have not vision problems or have access to a third party who is able to read and write a short message for them. Patients who have not speech, hearing and psychological problems. The age range is between 18-65 years. Exclusion criteria: Changes in the medication. Hospitalization for any reason. Patient's reluctance to continue working.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomized method: patients are divided to three groups (control group or interactive group or non-interactive group) with lottery. First patient enters one of three groups with lottery. The second patient also enters one of the other two groups with lottery. The third patient enters remains group without lottery. Lottery continues for each patient until each group enough to reach.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Science

Street address

Ghods St. Keshavarz Blvd. Tehran, Iran

City

Tehran

Postal code**Approval date**

2013-01-14, 1391/10/25

Ethics committee reference number

2627

Health conditions studied**1****Description of health condition studied**

Rheumatic heart valve diseases

ICD-10 code

I05, I06,

ICD-10 code description

Chronic rheumatic heart diseases

Primary outcomes**1****Description**

Adherence to treatment

Timepoint

Before the intervention, three months after the intervention.

Method of measurement

Self-report questionnaire, INR

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: this group is without intervention. Patients just fill the self report questionnaire before and three months after the intervention and with measurement International Normalized Ratio (INR) before and three months after intervention, their adherences are evaluated.

Category

Prevention

2**Description**

Non interactive group: for this group every week four educational messages is sent during three months by the researcher. The researcher has one way communication with the patients. Patients also, fill the self report questionnaire before and three months after the intervention and with measurement International Normalized Ratio (INR) before and three months after intervention, their adherences are evaluated.(Intervention 1)

Category

Prevention

3**Description**

Interactive group: for this group every week four educational messages is sent during three months by the researcher. Researcher has interact and two-way communication with patients. Number of messages is sent by the interaction are more than the group without interaction. Patients also, fill the self report questionnaire before and three months after the intervention and with the measurement International Normalized Ratio (INR) before and three months after intervention, their adherences are evaluated. (Intervention 2)

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Nadia Sedri

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Keshavarz Blvd. Tehran, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Vice Chancellor for Research, Tehran University of Medical Sciences. Ghods St. Keshavarz Blvd. Tehran, Iran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, 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**

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coach

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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