

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluating the effect of education and follow-up on readmission rates for the heart failure patients after discharge

Protocol summary

Summary

The main objective of this study was to determine the impact of education and follow-up on readmission rates for the heart failure patients after discharge. Major inclusion criteria were: stabilized heart failure, literacy, tendency of the patients to participate the study, minimum age of 20, telephone access. Major exclusion criteria were: stabilized psychiatric disorders, concurrent fatal disease, and severe hearing impairment. Design and setting: randomized, single blind, single center, placebo not used, trial phase 3. Study population included 120 patients with heart failure who were divided randomly with Block Randomization Method in two control and intervention groups, immediately after discharge. Demographic data of two groups were recorded. There are two parts of intervention; the first part is educating the patient and his/her family immediately after discharge, and also educational pamphlets were given to them. The second part is follow-up using phone call once a week in first month and then every two weeks in the later two months. In every phone call, the information about main outcome measures such as frequency readmissions, frequency outpatient physician visits, drug consumption, and improvement should be asked according to the control check lists. The patients will be guided according to their needs. But patients in control group get the routine care and had been called just every two weeks to record the information about primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051717727N1**

Registration date: **2014-08-23, 1393/06/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-23, 1393/06/01

Registrant information

Name

Nastaran Laal

Name of organization / entity

Shahid Beheshti university of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of education and follow-up on readmission rates for the heart failure patients after discharge

Public title

Effect of education and follow up on readmission for the heart failure patients after discharge

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria were: stabilized heart failure, literacy, tendency of the patients to participate the study, minimum age of 20, telephone access. Exclusion criteria were: stabilized psychiatric disorders, concurrent fatal disease, and severe hearing impairment.

Age

From **20 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

For the purpose of blinding random allocation was done with other person. Randomization Method: Block
Randomization was used to equalized the number of patients in both control and intervention groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Koodakyar Ave., Daneshju Blvd., Velenjak, Tehran

City

Tehran

Postal code

1985717443

Approval date

2014-05-25, 1393/03/04

Ethics committee reference number

400/982

Health conditions studied

1

Description of health condition studied

Related of education and follow-up on readmission rates for the Heart Failure Patients after discharge

ICD-10 code

Z74.3

ICD-10 code description

Need for continuous supervision

Primary outcomes

1

Description

Frequency of Hospital readmission in control and intervention groups

Timepoint

Every two weeks until three month after intervention

Method of measurement

Asking the patient

2

Description

Frequency of outpatient physician visits in control and intervention groups

Timepoint

Every two weeks until three month after intervention

Method of measurement

Asking the patient

3

Description

Drug consumption in control and intervention groups

Timepoint

Every two weeks until 3 month after intervention

Method of measurement

Asking the patient

4

Description

Improvement in control and intervention groups

Timepoint

Every two weeks until 3 month after intervention

Method of measurement

Asking the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: there are two parts of intervention; the first part is Patients and their family education about the life style, drug consumption, and warning signs were performed in 20 till 25 minutes immediately after discharge, according to the educational package endorsed by Community Medicine Specialist and Cardiologists, then educational pamphlets were given to

them. The second part is Phone call follow-up was performed once a week in first month and then every two weeks in the latter two months and the time spending on every session were 10 minutes which could be changed according to the patients' needs. In every phone call, the information about primary outcomes were asked and recorded according to the control check lists. The patients guided according to their needs, and their questions were answered.

Category

Prevention

2**Description**

Control group: Patients in control group get the routine care and had been called just every two weeks to record the information about primary data according to the control check lists and the time spending on every session was 5 minutes.

Category

N/A

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

Taleghani Hospital

Full name of responsible person

Dr.Afshin Mohammadalizadeh, Hospital administration

Street address

Taleghani Hospital, Velenjak St., Shahid Chamran Highway, Tehran

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

Shahid Beheshti university of Medical Sciences

Full name of responsible person

Dr.Hossein Goodarzi

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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

Shahid Beheshti 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**

Shahid Beheshti university of Medical sciences

Full name of responsible person

Nastaran Laal

Position

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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