

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Clinical trial of the comparison of the effect of clinical follow up and routine discharge plan on quality of life and hospitalization of patients with heart failure

Protocol summary

Study aim

The aim of this study was to determine the effect of clinical follow-up on quality of life and re-admission of patients with heart failure.

Design

It is a clinical randomized controlled trial study. 130 patients with heart failure who are referred to hospitals of Kerman University of Medical Sciences will be selected and randomly assigned to intervention or control groups. Randomization will be done through blocking method.

Settings and conduct

Sampling will be done at the Shafa Hospital of Kerman University of Medical Sciences. Randomization will be done using a randomized block design, the subjects are assessed and assigned through blocks of four (two in intervention and two in control group). Block randomization and statistical analysis are performed by a statistician who does not have information about patient randomization process.

Participants/Inclusion and exclusion criteria

Having heart failure and having no mental illnesses

Intervention groups

In the intervention group, the nurse will educate patient the post-discharge information. In the course of the clinical follow up the nurse will follow patients by telephone and refer them to the hospital in case of emergencies. The follow ups include medication control, regular exercise, and symptom relief. The control group will receive regular training during discharge.

Main outcome variables

The data will be collected using the quality of life questionnaire for patients with heart failure and hospitalization information. The quality of life questionnaire will be completed before the intervention and 3 months after the discharge. Re-admission and quality of life are two main outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100911004728N3**

Registration date: **2018-01-20, 1396/10/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-20, 1396/10/30**

Update count: **0**

Registration date

2018-01-20, 1396/10/30

Registrant information

Name

Hadi Ranjbar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 6862

Email address

ranjbar.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of the comparison of the effect of clinical follow up and routine discharge plan on quality of life and hospitalization of patients with heart failure

Public title
The effect of clinical follow-up on quality of life and re-admission of patients with heart failure

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with heart failure Who have tendency to participate in research ejection Fraction $\leq 40\%$ Pass at least one year from diagnosis New York Heart Association class III/IV heart failure Access to Follow-up for at least 3 month
Exclusion criteria:
 Previous history of dementia or other diseases based on medical records Valvular disease requiring surgery Other diseases that require readmission Work in health related professions such as medicine Heart transplantation has been done on him/her (Heart transplantation history)

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

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be performed using blocking. So that in each block two of the intervention group and two of the control group will enter.

Blinding (investigator's opinion)
Single blinded

Blinding description
The person responsible for data gathering and Statistician will not have access to patients randomization data.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Deputy of research, Kerman University of Medical Sciences, Jahad street

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2017-07-04, 1396/04/13

Ethics committee reference number

IR.KMU.REC.1395.196

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

Quality of Life

Timepoint

Before intervention, one, two and three months after discharge

Method of measurement

Heart failure Quality of life Questionnaire

2

Description

Readmission

Timepoint

Three months after Discharge

Method of measurement

Follow up

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Routine education and follow ups including Education about drugs, Diet, follow up visits and routine follow up plan of hospital

Category

Other

2

Description

Intervention group: Clinical follow up through telephone, visiting patients' home or invite them to visit the health facility

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Mansour Arab

Street address

Kosar Boulevard, Kerman

City

Kerman

Province

Kerman

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7618751151

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+98 34 3211 5780

Email

marab112004@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Research and technology Deputy, Ebne Sina St., Tahmasb Abbad Crossroad

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Email

marab112004@yahoo.com

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 of Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Medical University Campus, Kerman University of Medical Sciences, Haft-Bagh Highway, Kerman, Iran

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Fax**Email**

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Web page address**Email**

marab112004@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

All of the individual participant data collected during the
trial, after deidentification

**When the data will become available and for how
long**

Immediately following publication. No end date.

To whom data/document is available

Anyone who wishes to access the data.

Under which criteria data/document could be used

To gain access, data requestors will need to sign a data
access agreement. The data is available for any purpose.

From where data/document is obtainable

All applications should be sent to
marab112004@yahoo.com

**What processes are involved for a request to access
data/document**

All requests will be answered within a maximum of one
month by email.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer in Nursing

Latest degree

Master

Other areas of specialty/work

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