Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
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+98 21 6650 6862
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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 =< 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 Statisticianwill 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
Postal code
7618751151
Phone
+98 34 3211 5780
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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
City
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Postal code
7619813159
Phone
+98 34 3226 3719
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
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Medical University Campus, Kerman University of Medical Sciences, Haft-Bagh Highway, Kerman, Iran
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Person responsible for updating data

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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