

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison the effect of home-based education and active care versus usual care on self-care behavior, quality of life, 1year rehospitalization and survival of heart failure patients

Protocol summary

Study aim

To investigate the effect of home-care and education on self-care, quality of life, rate of re-hospitalization and mortality compared to conventional care in patients with chronic heart failure.

Design

Randomization of 128 patients with heart failure to two parallel groups, interventional and control groups, 64 patients in each group and outcome study

Settings and conduct

The hospitalized patients will be divided in two intervention and control groups. A questionnaire, (self care, demographic, SF-36 questionnaires and drugs) will be completed at the time of discharge for all patients. The intervention group will be educated monthly by a nurse at home up to six month. The control group will receive their usual care. After one year, all patients re-evaluated for the outcomes.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: acute heart failure, resident of Yazd; NYHA class II-IV. Exclusion Criteria: dementia, fatal associated disease such as cancer or dialysis and not acceptance by patients.

Intervention groups

interventional group: Patients with heart failure and Education of self care management at home every month for 6 months. Control group: Patients with heart failure and conventional care

Main outcome variables

Primary: rehospitalization and 1-year mortality rate
Secondary: means of self-care and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170522034081N2**

Registration date: **2019-06-07, 1398/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-07, 1398/03/17**

Update count: **0**

Registration date

2019-06-07, 1398/03/17

Registrant information

Name

mahdieh ghanbari firoozabadi

Name of organization / entity

Yazd Cardiovascular Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 3525 8354

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m.ghanbari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

99.980.000 rials

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of home-based education and active care versus usual care on self-care behavior, quality of life, 1year rehospitalization and survival of heart failure patients

Public title

Comparison the effect of home-based education and active care versus usual care on self-care behavior, quality of life and 1 year re-hospitalization and survival of patients admitted with acute heart failure in Afshar hospital

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

heart failure secondary to ischemic heart disease (IHD) and non-ischemic hear disease (NIH) on the basis of physician's diagnosis and patient's symptoms, and NYHA class II-IV being a native and resident of Yazd

Exclusion criteria:

dementia or any condition that hinders proper communication with the patient fatal associated disease that fosters the early death of the patient such as cancer or hemodialysis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. Tool used in randomization is random table is made with computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is blinded for care provider, investigator, outcome assessor, data analyser, data and safety monitoring board.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

shahid sadoughi blv., bahonar sq., Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8917945556

Approval date

2016-02-08, 1394/11/19

Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.407

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart disease

Primary outcomes

1

Description

Self care

Timepoint

Before intervention, 3 month, 6 month, 1 year after intervention

Method of measurement

The European 9-item self-care Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention, 3 month, 6 month, 1 year after intervention

Method of measurement

Sf-36 Quality of Life Questionnaire

2

Description

Rehospitalization

Timepoint

3 month, 6 month, 1 year after intervention

Method of measurement

Telephone call

3

Description

Death

Timepoint

3 month, 6 month, 1 year after intervention

Method of measurement

Telephone call

4

Description

6 minuet walk test

Timepoint

6 month, 1 year after intervention

Method of measurement

Doing 6 minuet walk test in cardiac rehabilitation center

Intervention groups

1

Description

Education and care at home

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar hospital

Full name of responsible person

Dr. Mahdieh Ghanbary Firoozabadi

Street address

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

dr. Amir Houshang Mehrparvar

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Shahid Sadoughi blv., Bahonar sq., Yazd

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Email

ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Azade sadat Poorhoseini

Position

Nutrition consultant

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

dr. Mohamad Hossein Soltani

Position

Heart Failure flow-ship

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data will be filled in SPSS.

When the data will become available and for how long

2020

To whom data/document is available

Every researchers in this field

Under which criteria data/document could be used

these data is available after getting justification.

From where data/document is obtainable

Mahdieh Ghanbari Firoozabadi, Physician of cardiac rehabilitation center, tel: 0098 353 525 83 54 Email: mahdieh_ghanbari@yahoo.com

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

After obtaining the license, the Vice-Chancellor of Information is available to the applicant.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Hakimeh Dadras

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Afshar hospital, jomhuri blv, yazd

City