Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of education and telephone follow-up on patients' adherence to the treatment regimen after myocardial infarction in patients admittede in Farshchian Cardiovascular Hospital of Hamadan in 2020

Protocol summary

Study aim

The aim of this study was to investigate the effect of educational intervention on adherence to the treatment regimen after myocardial infarction in patients admitted to Farshchian cardiovascular hospital in Hamadan in 2020.

Design

A randomized clinical trial with a control group, with three parallel groups

Settings and conduct

This study will be performed as a three-group clinical trial with the participation of 150 patients with myocardial infarction in Hamadan in 2020. Patients will be randomly assigned to be divided into three groups . In intervention group A , the necessary training will be provided using an booklet and face-to-face training . In the B intervention group, in addition to the above, patients will be monitored by telephone and vitual education for 3 months. Telephone calls will be made to patients following a follow-up twice a week for the first six weeks and then once a week for the second six weeks. There is no intervention in the control group and patients receive only routine care as usual.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Reading and writing literacy, Access to landline or mobile phone and the ability to use it, Age 35 to 70 years Exclusion criteria: No answering the phone (3 times), Lack of desire to continue participating in research

Intervention groups

In the intervention group A, the necessary training will be done by using the educational booklet for the importance of following the treatment regimes in the form of face-to-face training for each patient and also providing them with an educational booklet. In intervention group B , in addition to the above, patients will be monitored by telephone and virtual education for 3 months. There is no intervention in the control group(C) and patients receive only routine care .

Main outcome variables

Adherence to the treatment regimen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N31**
Registration date: **2020-07-18, 1399/04/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-18, 1399/04/28**
Update count: **0**

Registration date

2020-07-18, 1399/04/28

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education and telephone follow-up on patients' adherence to the treatment regimen after myocardial infarction in patients admittede in Farshchian Cardiovascular Hospital of Hamadan in 2020

Public title

The effect of educational intervention on patients' adherence to the treatment regimen

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age 35 to 70 years Access to landline or mobile phone and the ability to use it Reading and writing literacy

Exclusion criteria:

Lack of desire to continue participating in research No answering the phone (3 times)

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random allocation will be done using a random number table. Patients will be randomly divided into three groups intervention(A and B) and control (C).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.UMSHA.REC.1399.147

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21.01

ICD-10 code description

ST elevation (STEMI) myocardial infarction involving left main coronary artery

Primary outcomes

1

Description

A dherence to the treatment regimen

Timepoint

Two months after the educational intervention

Method of measurement

Questionnaire for following a treatment regimen

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: The necessary training will be provided using an educational booklet for the importance of following treatment regimens as face-to-face training for each patient and also providing them with an educational booklet.

Category

N/A

2

Description

Intervention group B: Patients will be monitored by telephone for 3 months. Phone calls will be made to patients following a follow-up treatment regimen twice a week for the first six weeks and then once a week for the second six weeks.

Category

N/A

3

Description
Control group C: No intervention is performed and patients receive only routine care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian cardiovascular hospital
Full name of responsible person
Mehdi Molavi Vardanajni
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Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
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s_bashirian@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy of research and technology
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
Hamedan University of Medical Sciences
Full name of responsible person
Mehdi Molavi Vardanajni
Position
Instructor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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