

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of self-administration of medication program on level of self-efficacy and medication adherence of patients with ischemic heart disease admitted in cardiac unit

Protocol summary

Study aim

Determine the effect of self-administration of medication program on self-efficacy and medication adherence of patients with ischemic heart disease admitted in the cardiac unit.

Design

Clinical trial with community based and pragmatic control group, with parallel group, without blindness, randomized with time block method

Settings and conduct

Patients with ischemic heart disease hospitalized in the Imam Reza hospital (AS) will be randomly selected and randomly assigned to the intervention and control groups (with time block in the selected section). In the intervention group, the self-administration of medication program will be performed in three steps. In the control group, the medication education and medication Consumption is routinely provided by the nurse in the same period. Pharmaceutical knowledge and self-efficacy in both groups will be checked before and after the intervention. The medication adherence will be measured 1 and 2 weeks after discharge by telephone.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be alert. Diagnosis of ischemic heart disease. No cognitive or psychological problem according to medical records. Have at least primary education. There is a tendency to take medications by the patient himself. Predict long-term (at least 6 months) consumption of two or more tablets at the time of discharge. Having a phone number to make calls after the discharge
Non-entry criteria: Discharge to a nursing home or a rehab center, or wherever that cause to patient deprivation of self-administration of medication. Unwillingness to follow-up with telephone after discharge.

Intervention groups

Patients with ischemic heart disease admitted in cardiac

unit under self-administration of medication program for 96 hour. In the control group, the use of medication will be done routinely.

Main outcome variables

Level of self-efficacy and medication adherence

General information

Reason for update

Update the date of completion of participant recruitment and completion of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20171223038022N1**

Registration date: **2018-05-20, 1397/02/30**

Registration timing: **prospective**

Last update: **2020-06-12, 1399/03/23**

Update count: **1**

Registration date

2018-05-20, 1397/02/30

Registrant information

Name

reza Haji ali beigloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3372 0518

Email address

hajjalibr951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-13, 1397/01/24

Expected recruitment end date

2018-07-15, 1397/04/24

Actual recruitment start date

2018-05-22, 1397/03/01

Actual recruitment end date

2018-08-22, 1397/05/31

Trial completion date

2018-09-06, 1397/06/15

Scientific title

The effect of self-administration of medication program on level of self-efficacy and medication adherence of patients with ischemic heart disease admitted in cardiac unit

Public title

The effect of self-administration of medication program on level of self-efficacy and medication adherence

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Be alert Diagnosis of ischemic heart disease is confirmed by clinical signs, ECG and enzyme tests by a cardiologist. No cognitive or psychological problem according to medical records. Do not have audible(Complete hearing despite the use of aids) and visual(Ability to read newspaper at a distance of 30 cm with glasses)problems. Age under the 60 and over 18. Have at least primary education level. There is a tendency to take medications by the patient himself. Predict long-term (at least 6 months) consumption of two or more tablets at the time of discharge. Having a phone number to make calls after the discharge

Exclusion criteria:

Discharge to a nursing home or a rehab center, or wherever that cause patient deprivation of self-administration of medication. Unwillingness to follow-up with telephone after discharge.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The research units according to the sequences that generated by SPSS software before the start of the study were randomly divided into intervention and control groups. In order to prevent the dissemination of information between the two groups, patients in the same room in two groups will not be used.

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 Mashhad University of Medical Sciences

Street address

University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-04-10, 1397/01/21

Ethics committee reference number

IR.MUMS.REC.1396.381

Health conditions studied**1****Description of health condition studied**

Ischemic Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic Ischemic Heart Disease, Unspecified

Primary outcomes**1****Description**

Self-Efficacy For Appropriate Medication Use

Timepoint

At the beginning of the study (before the intervention) and 96 hours after the intervention

Method of measurement

Self-Efficacy For Appropriate Medication Use scale

2**Description**

Level of medication adherence

Timepoint

1 and 2 weeks after discharge

Method of measurement

Morisky medication adherence scale

Secondary outcomes

1

Description

Evaluation level of knowledge

Timepoint

24 after admission and upon discharge

Method of measurement

Instrument to evaluate the level of knowledge

2

Description

Assessment of patients' satisfaction with type of medication use

Timepoint

At the time of discharge

Method of measurement

Patients' Satisfaction of type of medication Use scale

3

Description

Nurses' Satisfaction with self-administration of medication program

Timepoint

At the end of the first, second and third months of study

Method of measurement

The Nurses 'Satisfaction from the implementation of self-administration of drug management program in the hospital instrument

Intervention groups

1

Description

Intervention group: In the intervention group, in the first 24 hours, the nurse will be responsible for providing medications and training of medication administration. This training will include the name of the medication, the dosage, the method and timing of the medication, the cause of medication use and possible side effects for the patient. Brochures for each medication will be provided to patients in order to further training. Immediately after completing this stage, the patient's ability to start the second phase is assessed by the checklist number one and, if it is eligible, will enter the second stage of the program. At this stage (second step), the next 24 hours of the patient's medicine will be placed inside a special box that will be available to the patient and can be locked, and the numbered key is provided to nurses at a special place at the nursing station. Then, according to the trained patient in the first stage, the patient will ask his nurse at the appropriate time. After nurse presence, he will remove the relevant medications from the box and will use it with direct supervision of the nurse and after confirmation of the correctness of the medication taken. If needed, blood pressure, pulse, and other vital signs will be controlled by the nurse before taking the medicine, and the patient

will be given appropriate training in this regard. Furthermore, the nurse will provide a checklist for patient that named "used medication checklist" to complete the list after taking the medication. This checklist is designed to ensure that the correct medication is taken at the right time. This checklist is also provided to prevent the medication from being missed or reused because of doubt about the use of the medication and will be seen by the nurse in each shift. If the patient delays the authorization for medication use for 1 hour medication consumption will be reminded and This issue is considered as the first indication of lack of readiness and if it happen in next time, patient will comeback to first step and will use his medication with nurse help. This process is repeated up to 2 times and if the patient is unable to take medication by himself, he will be excluded from the study. At the end of the 24th hour (second stage), the amount of the ability, competence and adequacy of medication use is assessed by the checklist number 3. If used correctly and on time, these medication at the end of the 24 hour second (according to checklist 3), the patient's next 48 hours medication is placed in the patient's personal box and a copy of the key is given to him and the patient will be responsible for keeping the key to himself and taking Medications and the nurse will be responsible for indirect control by counting the pills. This count will take place at certain hours (6:30 am, 12:30 and 6:30 PM). At this stage, the patient will be required to complete a checklist of consumed medications to prevent any of mentioned problems and the checklist will be controlled by the nurse. Possible errors will be recorded and reported at this stage.

Category

Other

2

Description

Control group: In the control group, the medications are given to the patients by the nurse, and patients will receive routine drug training during admission and at the time of discharge.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Seyed Reza Mazlom

Street address

Imam Reza Square, Ebne Sina street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

emamreza@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

University ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

vpresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Reza Haji Ali Beigloo

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Campus University,End of Shahid Bahonar Blvd ,Vakil

Abad 2 ,Vakil Abad

City

mashhad

Province

Razavi Khorasan

Postal code

9177948988

Phone

+98 936 186 6829

Email

rezahajialibeigloo@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reza Haji Ali Beigloo

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Campus University,End of Shahid Bahonar Blvd ,Vakil Abad 2 ,Vakil Abad

City

MASHHAD

Province

Razavi Khorasan

Postal code

9177948988

Phone

+98 936 186 6829

Email

rezahajialibeigloo@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reza Haji Ali Beigloo

Position

Master of Science in Nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 110, Payam Ave., Heydar Baba Blvd.,Shahriar Town

City

Urmia

Province

West Azarbaijan

Postal code

9177948988

Phone

+98 44 3372 0518

Fax**Email**

hajialibr951@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available