

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Assessment of the effect of patient education and follow up with short massage on adherence to therapeutic regimen of the patients with acute coronary syndrome after discharge of coronary care units.

Protocol summary

Study aim

Determination of the effect of patient education and follow up with short massage on adherence to therapeutic regimen with acute coronary syndrome after discharge

Design

This is a parallel clinical trial, pragmatic, community based with two intervention and a control group. The subjects will allocate to each group through a random block approach. Each block have a sample of each group. Then, each block randomly will be selected of one of the six possible state. In this study, blindness is not possible.

Settings and conduct

In the clinical trial study, 111 patients with acute coronary syndrome who hospitalized in the coronary intensive care units, 5th of Azar and Sayyad Shirazi in Gorgan; Amiralмомenin in Kordko city and Al-Jalil in Ahgala city will be selected through convenient sampling and then, will be designated randomly into three groups. The first and second groups will be educated through a booklet about adherence of treatment by the researcher. Then they will receive the booklet. The second group will be followed by short message after discharge for 2 months. The control group will only receive routine pre-discharge training. Two months after the discharge, the adherence questionnaire will be completed for each patient in the heart clinic or patient home. In the study blinding is not possible.

Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects' age between 25 - 75 years, confirming patients' acute coronary syndrome by a Cardiologist, having an active Mobile and SMS program (short message service). Exclusion criteria : Not having sensory perception or mental retardation Not having advanced disease such as censer.

Intervention groups

Group1: Training booklet group2: Training, Booklet and

Follow-up Group3: Control

Main outcome variables

Treatment regimen adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180911041002N1**

Registration date: **2019-01-22, 1397/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-22, 1397/11/02**

Update count: **0**

Registration date

2019-01-22, 1397/11/02

Registrant information

Name

Zoleikha Ghoreishi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3242 6900

Email address

ghoreishi.z@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of patient education and follow up with short massage on adherence to therapeutic regimen of the patients with acute coronary syndrome after discharge of coronary care units.

Public title

Effect of patient education and follow up with short massage on patient's therapeutic adherence with heart disease.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 25 to 75 years old Acute coronary syndrome diagnosis approved by a cardiologist physician Ability to speak and understanding Persian language by patient or relatives Ability to using mobile by patient or relatives Having active mobile and ability to send SMS by patient or relatives Achieving adherence score less than 50%

Exclusion criteria:

Not having other advanced disease, such as cancer, diabetes Not having diagnosed mental disorder Unwillingness to participate in research by patient or relatives Lack of access to the patient after discharge

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **111**

Randomization (investigator's opinion)

Randomized

Randomization description

We have three groups in this study. Group A = training with booklet, Group B = training with booklet and follow-up with SMS, and Group C = Control group. In this study, we have 111 samples, each of which contains 37 patients. For block randomization, the simplest and smallest production block will be 3 blocks (3 = the number of groups under investigation). Therefore, we have 6 states including 1. ABC, 2. CAB, 3. CAB, 4. BCA, 5. BAC, 6. ABC. To execute, we will use a regular hexagon (6 sided dice) that each side of dice is attributed to one of the 1 to 6 above states. So, by each throwing a dice, one of these situations arises. By 37 throwing the dice, we have 37 triple block that randomly created. Example: ABC, BAC, BAC, CBA, ABS, CAB, = 37 Triple Block

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 Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Shast-Kola Road, Saari Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2018-09-03, 1397/06/12

Ethics committee reference number

IR.GOUMS.REC.1397.102

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

Acute Coronary Syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute ischaemic heart disease, unspecified

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

Adherence to the treatment regimen

Timepoint

At the beginning of the study and 2 months after the patient's discharge

Method of measurement

Adherence to treatment questionnaire-self report

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will be educated about adherence the drug orders, the type of medications used by the patient, the importance of adherence of medication orders, unwanted side effects of drugs, considering doses of medication, taking on time, emergency medicines, diet and permitted exercise. The second group: In addition to teaching the above, short message will be sent about the times and drug using, attention to dosage, diet, and mobility are at the acceptable level. These training take place in two sessions and each session about 45 minutes.

Category

Behavior

2

Description

Second intervention group: training, booklet, Follow-up reminder short messages Patients are trained in the ward on the patient's bedside for a half to an hour before discharge by the researcher. The booklet has been prepared by a researcher and confirmed by a cardiologist and dietitian. Within two months after the discharge, 3 times a week, a reminder message will be sent to the patient. Two months after discharge the adherence questionnaire, researcher at the Patient's Home or Heart Clinic will complete the face-to-face interview.

Category

Behavior

3

Description

Control group will receive only routine training before discharge of the ward. Two months after discharge of the patients, they will complete the adherence questionnaire in their home or in clinical heart disease department through face-to-face interview by researcher.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi hospital in Gorgan

Full name of responsible person

Zoleikha Ghoreishi

Street address

Shahid Sayyad Shirazi hospital, Shahid Sayyid Shirazi Blvd.

City

Gorgan

Province

Golestan

Postal code

4917867439

Phone

+98 17 3215 1502

Fax

+98 17 3226 1175

Email

infosayyad@goums.ac.ir

2

Recruitment center

Name of recruitment center

5 Azar hospital

Full name of responsible person

Zoleikha Ghoreishi

Street address

5 Azar street

City

Gorgan

Province

Golestan

Postal code

4917763681

Phone

+98 17 3222 0561

Email

pr-5azar@goums.ac.ir

3

Recruitment center

Name of recruitment center

Amir Almomenin Kordkoy hospital

Full name of responsible person

Zoleikha Ghoreishi

Street address

Forest Avenue

City

Kordkoy

Province

Golestan

Postal code

4881899441

Phone

+98 17 3432 5769

Fax

Email

h.kordkoy@goums.ac.ir

4

Recruitment center

Name of recruitment center

Al Jalil Aq Qala Hospital

Full name of responsible person

Zoleikha Goreishi

Street address

Aqqala Bandar Turkman Road

City

Aqqala

Province

Golestan

Postal code

4931313946

Phone

+98 17 3452 6767

Email

alejalil-H@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

Street address

Golestan University of Medical Sciences, Sari Road,
Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3242 6900

Fax

+98 17 3245 5171

Email

Honarvar@goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Gholam Reza Mahmoodi-shan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

Street address

Golestan University of Medical Sciences, Sari Road,

Gorgan

City

Gorgan

Province

Golestan

Postal code

4918936316

Phone

+98 17324551660

Fax

+98 17 3242 1657

Email

mahmoodigh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Zoleikha Ghoreishi

Position

Critical Care Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursing

Street address

Golestan University of Medical Sciences, Sari Road,
Gorgan

City

Gorgan

Province

Golestan

Postal code

4918936316

Phone

+98 17324551660

Fax

Email

ghoreishi.z@goums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Zoleikha Ghoreishi

Position

Critical care nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursing

Street address

Golestan University of Medical Sciences, Sari Road,
Gorgan

City

Gorgan

Province

Golestan
Postal code
4918936316
Phone
+98 17 3245 1660
Fax
+98 17 3245 5171
Email
ghoreishi.z@goums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Yes - There is 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

Results of the study will be published as an article. The ethical principle will be respected during preparation of the article for publishing.

When the data will become available and for how long

Accessibility of the data can be started 6 months after publishing the results of the study as an article.

To whom data/document is available

Only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The results could be used for scientific purposes with citing to the article published.

From where data/document is obtainable

4918936316 TEL_01732451660 Fax_4421657, Golestan University of Medical Sciences, Sari Road, Gorgan, IRAN

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

Scholar valid documents and the title of study must be sent and the study must be about adherence of therapeutic regime in patient with acute coronary syndrome.

Comments