

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of Cardiac rehabilitation educational program on risk factors and functional capacity of patients with coronary artery disease in Ali ibn abitaleb hospital, Zahedan, 1397

Protocol summary

Study aim

Determining the effect of cardiac rehabilitation program on risk factors and functional capacity of patients with coronary artery disease

Design

Semi-experimental study with control group on patients with coronary artery disease admitted to CCU units, Parallel groups, available sampling method, weekly coin thrown to determination control or intervention week . The sample size is 35 in each group.

Settings and conduct

Patients with coronary artery disease admitted to CCU of Ali ibn Abitalib hospital in Zahedan

Participants/Inclusion and exclusion criteria

Diagnosis of coronary artery disease is done by a specialist, confirming the results of diagnostic tests ;The first hospital admission is due to coronary artery disease; Ejection fraction is between 25 to 40%; The hemodynamic status at the start of the rehabilitation program is stable; Age between 25 and 65 years old; Ability to walk without help; Reside in Zahedan City There is no serious arrhythmia when the rehab program starts; Have not COPD, pulmonary artery pressure and right heart problems; Lack of history of heart surgery and not being a candidate for CABG

Intervention groups

For the intervention group, four sessions are scheduled at the time of discharge: 1st, 2nd, and 3rd weeks after that. The content of the sessions include the benefits of walking in reducing risk factors, the importance of cardiac rehab and treatment follow-up, training Risk factors, diet and management education, lifestyle changes. In every training session, checklists are monitored and evaluated . During the sixth, eighth and tenth weeks after the discharge, a phone call will be made to patients to check the patient's compliance with the activity schedules. The control group will receive only

routine hospital training at the time of discharge.

Main outcome variables

Blood glucose, Blood lipid profile, Functional capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180110038298N2**

Registration date: **2018-08-01, 1397/05/10**

Registration timing: **prospective**

Last update: **2018-08-01, 1397/05/10**

Update count: **0**

Registration date

2018-08-01, 1397/05/10

Registrant information

Name

Morteza Barani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

Email address

m.barani@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-03, 1397/05/12

Expected recruitment end date

2018-12-03, 1397/09/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Cardiac rehabilitation educational program on risk factors and functional capacity of patients with coronary artery disease in Ali ibn abitaleb hospital, Zahedan, 1397

Public title

The effect of Cardiac rehabilitation educational program on risk factors and functional capacity of patients with coronary artery disease

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of coronary artery disease is done by a specialist, confirming the results of diagnostic tests The first hospital admission is due to coronary artery disease Ejection fraction is between 25 to 40% The hemodynamic status at the start of the rehabilitation program is stable Age between 25 and 65 years old Ability to walk without help Reside in Zahedan City

Exclusion criteria:

There is no serious arrhythmia when the rehab program starts Have not COPD, pulmonary artery pressure and right heart problems Lack of history of heart surgery and not being a candidate for CABG

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **2**

Initially and before the start of the program, a blood sample for fat profile and suger are obtained and then compared at the end of the intervention by re-sampling.

Randomization (investigator's opinion)

Not randomized

Randomization description**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 zahedan university of medical Sciences

Street address

NO. 1 , Daneshgah Ave., Hesabi Squ., Pardis complex , university of medical sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR.ZAUMS.REC.1397.125

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

Cardiovascular disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

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

Cardiac Rehabilitation educational Program

Timepoint

Before discharge and then the end of the study in the twelfth week

Method of measurement

blood sample, 6 minute walk test

Secondary outcomes**1****Description**

Blood glucose

Timepoint

Before discharge and then the end of the study in the twelfth week

Method of measurement

blood sample

2**Description**

Blood lipid profile

Timepoint

Before discharge and then the end of the study in the twelfth week

Method of measurement

blood sample

3

Description

Waist Circumference

Timepoint

Before discharge and then the end of the study in the twelfth week

Method of measurement

Measuring with meter

4

Description

Waist-hip ratio

Timepoint

Before discharge and then the end of the study in the twelfth week

Method of measurement

The number obtained by dividing the waist circumference of the hip circumference

5

Description

6 minute walk test

Timepoint

Before discharge and then the end of the study in the twelfth week

Method of measurement

The distance traveled in a six minute walk test per meter

Intervention groups

1

Description

Intervention group: Includes 35 patients undergoing a cardiac rehabilitation program within twelve weeks. The program consists of four lecture sessions and a questionnaire that focuses on the risk factors for cardiovascular disease including blood sugar and lipids, and hypertension, which, prior to discharge, are dispensed in the first week after discharge. The second and third weeks are held. In addition, the patient follows a daily walking program at least three times a week during the study period, which increases the heart rate by 10% on a weekly basis. Before the intervention, and at the end of the twelfth week blood tests are performed, including blood sugar and blood lipids. Blood pressure, waist circumference and waist to hip ratio and distance traveled in the six-minute walk test are compared at the beginning and end of the study.

Category

Rehabilitation

2

Description

Control group: Includes 35 eligible patients who receive routine hospital training. Blood glucose and blood tests are done prior to discharge and at the end of the study. Record the blood pressure and distance traveled in the 6-minute walk test at the time of discharge and in the 12th week and compare with the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abitaleb Zahedan Hospital

Full name of responsible person

Mohammad Kazem Moemeni

Street address

No. 1, Persian Gulf Highway, Blvd.Salamat, Ali Ibn Abi Talib haospital

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

alihos_zah@yahoo.com

Web page address

<http://alihos.zaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noormohammad Bakhshai

Street address

No. 1, NO. 1 , Daneshgah Ave., Hesabi Squ., Pardis complex , University of medical sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3341 6708

Email

public@zaums.ac.ir

Web page address

<http://www.zaums.ac.ir>

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Azam Shabazi Dehsookhte

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 1, Behdasht Blvd., Mashahir square, Faculty of Nursing and Midwifery

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3344 2482

Email

shahbazi.azam92@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Fariba Yaghubi Nia

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No. 1, Behdasht Blvd., Mashahir square, Faculty of Nursing and Midwifery

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3343 0059

Fax

+98 54 3344 2481

Email

yaghoubinia@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Azam Shabazi Dehsookhte

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 1, Behdasht Blvd., Mashahir square, Faculty of Nursing and Midwifery

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3344 2482

Email

shahbazi.azam92@gmail.com

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