

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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**

alios\_zah@yahoo.com

**Web page address**

<http://alios.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