

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 2026

### The effect of eight weeks cardiac rehabilitation program on lxr gene expression and serum tnf level in cabg patients

#### Protocol summary

##### Study aim

The effect of eight weeks cardiac rehabilitation on LXR gene expression and serum TNF $\alpha$  levels in CABG patients.

##### Design

In the present clinical practice, subjects were 24 CABG middle aged male patient who were randomly assigned into two group: control (n=12), and combination training (n=12) groups. Each person in the community was given a card number and then put all the cards in a box and after mixing them into the box, randomly drawn the numbers out of order. And so we select the two training and control groups. This research is of non blind type.

##### Settings and conduct

The study was conducted at Javad Alaemeh Hospital in Mashhad under the supervision of a resident physician in the cardiac rehabilitation ward of the hospital and with a combined rehabilitation program of Strength and aerobic exercise (specified protocol) for eight weeks, three sessions per week for cabg patients. 24 hours before and 48 hours after the last cardiac rehabilitation session, all subjects' blood samples will be taken.

##### Participants/Inclusion and exclusion criteria

\_No systolic blood pressure greater than 160 mmHg and diastolic higher than 100 mmHg \_Not using walking aids like walking canes and walkers

##### Intervention groups

Exercise group, performed eight weeks Cardiac Rehabilitation Combined Exercise ( Strength and aerobic). 24 hours before and 48 hours after the last cardiac rehabilitation session, all subjects' blood samples in two groups of control and exercise were taken and plasma and monocyte isolation were performed to measure the indices, then training group were compared with control group.

##### Main outcome variables

TNF alpha LXR

#### General information

##### Reason for update

##### Acronym

CABG

##### IRCT registration information

IRCT registration number: **IRCT20191230045945N1**

Registration date: **2020-01-12, 1398/10/22**

Registration timing: **retrospective**

Last update: **2020-01-12, 1398/10/22**

Update count: **0**

##### Registration date

2020-01-12, 1398/10/22

##### Registrant information

##### Name

FAHIMEH PARHIZI

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3502 9210

##### Email address

parhizif1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-30, 1398/08/08

##### Expected recruitment end date

2019-12-01, 1398/09/10

##### Actual recruitment start date

2019-11-01, 1398/08/10

##### Actual recruitment end date

2019-12-11, 1398/09/20

##### Trial completion date

2019-12-11, 1398/09/20

## Scientific title

The effect of eight weeks cardiac rehabilitation program on lxr gene expression and serum tnf level in cabg patients

## Public title

"Effect of cardiac rehabilitation in CABG patients"

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Men age 40\_60. Cognitive, visual and auditory health. No systolic blood pressure greater than 160 mmHg and diastolic higher than 100mmHg. Not using walking aids like walking canes and walkers. Avoid doing exercise or exercise activities while participating in research.

### Exclusion criteria:

Having dangerous arrhythmias and ECG changes Severe respiratory problems that prevent you from exercising

## Age

From **45 years** old to **60 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **24**

More than 1 sample in each individual

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

Tnf alpha\_ lxr

Actual sample size reached: **24**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Tnf alpha\_ lxr

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, each person in the target population was assigned a card number and then put all the cards in a box and after mixing them into the box, randomly and without any special sequence of numbers. Drag and drop the two groups of exercise and control.

## 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 committe of Azad eslamic university of neyshapior

## Street address

Eghbal lahoury blv.25 street. No.29

## City

Mashhad

## Province

Razavi Khorasan

## Postal code

11111111

## Approval date

2019-07-18, 1398/04/27

## Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1398.016

## Health conditions studied

### 1

#### Description of health condition studied

Atherosclerosis\_CABG

#### ICD-10 code

I25.708

#### ICD-10 code description

Atherosclerosis and coronary artery bypass graft(s)

## Primary outcomes

### 1

#### Description

Lxr gene expression

#### Timepoint

24 hour before the start of the rehabilitation period and 48 hour after the end of the cardiac rehabilitation period

#### Method of measurement

10 ml of blood was collected from the brachial vein of the participants and measured by a Real-time polymerase chain reaction in the laboratory.

### 2

#### Description

Tnf alpha

#### Timepoint

24 hour before the start of the rehabilitation period and 48 hour after the end of the cardiac rehabilitation period

#### Method of measurement

10 ml of blood was collected from the brachial vein of the participants and measured by elisa in the laboratory.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, 12 cabgg men

underwent eight weeks of strength and aerobic rehabilitation program in Javad Al-e-Ameh Hospital in Mashhad. They will be examined by ELISA and real\_time pcr.

**Category**

Rehabilitation

**2****Description**

Control group: In this group, 12 patients without cardiac rehabilitation program were considered as the comparison group. Blood samples were taken from the patients before and after the beginning of the study to evaluate tnfr and lxr and were compared.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Java alameh hospital

**Full name of responsible person**

Dr. Emad Alavi Nia

**Street address**

Mashhad,vakilabad blv,honarestan road.javad alameh hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9178613111

**Phone**

+98 51 3881 6010

**Fax**

+98 51 3883 8103

**Email**

info@jhosp.org

**Web page address**

http://javadaemehosp.ir/

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Amir Rashid lamir

**Street address**

Khorasan Razavi Province, Neyshabour, Abbey Road

**City**

Neyshabur

**Province**

Razavi Khorasan

**Postal code**

9319975853

**Phone**

+98 51 4262 1901

**Fax**

+98 51 4261 5472

**Email**

Neyshabur@iau-Neyshabur.ac.ir

**Web page address**

Http://www.iau-Neyshabur.ac.ir/

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

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

20

**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**

Islamic Azad University

**Full name of responsible person**

Fahimeh Parhizi

**Position**

Nurse- Sports coach

**Latest degree**

Master

**Other areas of specialty/work**

Physical Medicine

**Street address**

Iqbal Lahori Boulevard;

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1111111111

**Phone**

+98 51 3502 9210

**Email**

Parhizif1@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Fahimeh Parhizi

**Position**

Nures- Sport coach  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physical Medicine  
**Street address**  
Mashhad.eghbal lahouri blv.25 street.number 29  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
1111111111  
**Phone**  
+98 51 3502 9210  
**Fax**  
**Email**  
Parhizif1@mums.AC.IR

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Fahimeh Parhizi  
**Position**  
Nurse- Sports coach  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physical Medicine  
**Street address**  
Iqbal Lahori Boulevard;  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**

1111111111

### Phone

+98 51 3502 9210

### Email

Parhizif1@mums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Only the main part related to the original consequence is shared after unidentifiable.

### When the data will become available and for how long

The period of access to documentation and data files is one year after the results are published

### To whom data/document is available

Access for researchers working in academic institutions

### Under which criteria data/document could be used

No special conditions.

### From where data/document is obtainable

Refer to responsible author by email

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

It will be requested through the email address and will be tracked as soon as possible

### Comments