# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 TNFα 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 lahouri blv.25 street. No.29
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
\\\\\\\\\\
**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 tnf alpha 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

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info@jhosp.org

**Web page address**

http://javadalaemehosp.ir/

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Amir Rashid Iamir

**Street address**

Khorasan Razavi Province, Neyshabour, Abbey Road

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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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Fahimeh Parhizi

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**Latest degree**

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## 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**