

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Effect of a period of combined training on Leptin, Adiponectin and Resistin in Middle-aged men after Coronary artery bypass surgery (CABG)

#### Protocol summary

##### Study aim

Effect of a period of combined training on Leptin, Adiponectin, and Resistin in Middle-aged men after Coronary artery bypass surgery (CABG)

##### Design

The sample will be picked among the population and with respect to entry condition to test voluntarily and based on availability. 26 men who undergone bypass surgeries in the 40-60 age range and by available sampling method will be selected, and randomly they were categorized into 12 and 14 individuals experimental and control.

##### Settings and conduct

Cardiac Rehabilitation Center of Javad Al-A'meh Cardiovascular Hospital, Mashhad

##### Participants/Inclusion and exclusion criteria

-In the 40-60 age range -Being interested to participate in research -Hearing, cognitive and visual health -systolic blood pressure higher than 160 mmHg and diastolic blood pressure -higher than 100 mmHg - Lack of suffering from acute and specific diseases that prevent doing exercises -The subjects who were taking the same medications -Not use of neurological medications -Not use of aid equipment to walk e.g by cane and walker ..... -the occurrence of ventricular arrhythmias -to be observed Myocardial Infarction in the ECG during training sessions -respiratory disorders during rehabilitation and training -unstable angina

##### Intervention groups

Combined aerobic and resistance training

##### Main outcome variables

Independent variables: eight-week aerobic and resistance exercise rehabilitation program. Related variables: Independent variable: Combined rehabilitation exercises, dependent variable: Leptin, adiponectin, and resistin factors.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201031049202N1**

Registration date: **2020-11-13, 1399/08/23**

Registration timing: **retrospective**

Last update: **2020-11-13, 1399/08/23**

Update count: **0**

##### Registration date

2020-11-13, 1399/08/23

##### Registrant information

##### Name

Hossein Nikkar

##### Name of organization / entity

Islamic azad University, Neyshabour branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3243 0381

##### Email address

h.nikkar@iau-neyshabur.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-04, 1399/07/13

##### Expected recruitment end date

2020-10-11, 1399/07/20

##### Actual recruitment start date

2020-10-11, 1399/07/20

##### Actual recruitment end date

2020-11-03, 1399/08/13

##### Trial completion date

2020-11-03, 1399/08/13

## Scientific title

Effect of a period of combined training on Leptin, Adiponectin and Resistin in Middle-aged men after Coronary artery bypass surgery (CABG)

## Public title

Effect of a period of combined training on Leptin, Adiponectin, and Resistin in Middle-aged men after Coronary artery bypass surgery (CABG)

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

In the 40-60 age range Being interested to participate in research Hearing, cognitive and visual health systolic blood pressure higher than 160 mmHg and diastolic blood pressure higher than 100 mmHg Lack of suffering from acute and specific diseases that prevent doing exercises The subjects who were taking the same medications Not use of neurological medications Not use of aid equipment to walk e.g by cane and walker

### Exclusion criteria:

Cardiac arrhythmia o be observed Myocardial Infarction in the ECG during training sessions respiratory disorders during rehabilitation and training unstable angina

## Age

From **40 years** old to **60 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **26**

Actual sample size reached: **26**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

thics committee of Islamic Azad University, Neyshabur Branch

##### Street address

Research Blvd., Islamic Azad University , Neyshabour

Branch, Neyshabour, Khorasan Province, Iran

#### City

Neyshabur

#### Province

Razavi Khorasan

#### Postal code

9319975853

#### Approval date

2020-09-24, 1399/07/03

#### Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1399.012

## Health conditions studied

### 1

#### Description of health condition studied

Coronary artery bypass graft patients

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Percentage of people who underwent coronary artery bypass grafting

#### Timepoint

before cardiac rehabilitation period and end of it.

#### Method of measurement

Patients ECG, condition of physical fitness, Cardiovascular and Ejection Fraction (EF) risk factors, the Rehabilitation program results

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Rehabilitation program (aerobic, resistance training), 26 men who undergone bypass surgeries in the 40-60 age range, and by available sampling method will be selected, and randomly they were categorized into two groups. 14 individuals experimental group. Participants as an experimental group in the rehabilitation center of Javadlameh Heart Hospital completed exercises and In order to reduce the mediator and mixer effect in research, according to aspects of control the short-term effects of the diet based on the desired indicators, in this session, the doctor recommended eating ready meals at least 24 hours before exercise program and blood sampling. they avoided caffeinating beverages and similar diets. Thus, 14 people (combined exercise group) be selected. Examples in the same environment and conditions have performed combined sports activities.

#### Category

Lifestyle

## 2

### Description

Control group: (Patients without rehabilitation program):26 men who undergone bypass surgeries in the 40-60 age range, and by available sampling method will be selected, and randomly they were categorized into two groups.12 individuals control group, the control group included those who person that didn't participate in the cardiac rehabilitation program after surgery and haven't any regular physical activity and In order to reduce the mediator and mixer effect in research, according to aspects of control the short-term effects of the diet based on the desired indicators, in this session, the doctor recommended eating ready meals at least 24 hours before exercise program and blood sampling. they avoided caffeinating beverages and similar diets. Thus,12 people (control group) be selected. Examples in the same environment and conditions have performed combined sports activities.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rehabilitation Center of Javad Allameh Hospital

##### Full name of responsible person

Dr. Emad Alavinia

##### Street address

Honarestan Blvd, Mashhad, Khorasan Province, Iran

##### City

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##### Province

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##### Postal code

9178613111

##### Phone

+98 51 3881 6010

##### Email

info@jhosp.org

##### Web page address

http://javadalaemehosp.ir/

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Allameh Hospital

##### Full name of responsible person

Dr. Emad Alavinia

##### Street address

Honarestan Blvd, Mashhad, Khorasan Province,Iran

##### City

Mashhad

#### Province

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#### Postal code

9178613111

#### Phone

+98 51 3881 6010

#### Email

info@jhosp.org

#### Web page address

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Allameh Hospital

#### Proportion provided by this source

50

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Ferdowsi University of Mashhad

##### Full name of responsible person

Dr. Amir Rashidlamir

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Exercise physiology, metabolism and biochemistry

##### Street address

Azadi Square, Ferdowsi University, Mashhad,Razavi khorasan province, Iran

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##### Web page address

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ferdowsi University of Mashhad

**Full name of responsible person**

Amir Rashid Lamir

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise physiology, biochemical and metabolism

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

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

some sections of results about some information on the main outcome can be shared.

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

the access time is period from 1399 onwards

**To whom data/document is available**

Only supervisors and advisors

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

for use, it must be coordinated with supervisors, consultants, and researchers

**From where data/document is obtainable**

Hossein Nikkar h.nikkar@iau-neyshabur.ac.ir

09151601391 Dr. Amir Rashidlamir

amir.rashidlamir@gmail.com 09151514174

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

First, the request should be given to the supervisors and advisors. After their approval, the data will be assigned.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University, Neyshabur Branch

**Full name of responsible person**

Dr Rambod Khajei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise Physiology

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Research Blvd., Islamic Azad University, Neyshabour, Khorasan Razavi Province, Iran

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