

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of eight weeks resistance training in land and water on lipid profile change and the blood mononuclear cells PPAR- α and ABCG8 gene expression in middle-aged women after Coronary Artery Bypass Grafting

Protocol summary

Study aim

Regarding the relationship between reverse cholesterol transport and cardiovascular diseases, the positive effect of physical activities on key factors affecting this process the current study is aimed at examining PPAR α gene expression in peripheral blood mononuclear cells (PBMNCs) in middle-aged women having had CABG, after 8 weeks of aquatic and dryland resistance training programs.

Design

In this research, thirty cardiac patient volunteer (aged 43-56 years) who meet the inclusion criteria will be selected for this study from the entire population.

Settings and conduct

This research is carried out as per-test and post-test. Middle-aged women with cardiovascular disease that refer to Shafa Hospital in Kerman will include. Fasting blood samples will take from all participants 48 hours both before the beginning and after the last training session. PPAR α and ABCG8 relative gene expression will identify by Real-Time PCR method from PBMN cells.

Participants/Inclusion and exclusion criteria

Patients were included in the study if they had undergone coronary artery bypass 3 months before the study and were relatively fit to carry out the exercises and . Patients were excluded from this study if they had unstable angina, decompensated heart failure, myocardial infarction , problematic ventricular arrhythmias

Intervention groups

Following a random screening, the participants were divided into control group , the aquatic resistance training group and dryland resistance training group .Exercise training protocol includes eight weeks of resistance training (3 days a week / 60 minutes per session) and consisted of warm-up (10 minutes), main activity (30 to 40 minutes) and cooling down (10

minutes) . In this period control group will have no physical activity except doing things everyday life.

Main outcome variables

Improve physical function, improve mental and social status of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180113038343N1**

Registration date: **2018-02-19, 1396/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-19, 1396/11/30**

Update count: **0**

Registration date

2018-02-19, 1396/11/30

Registrant information

Name

Leili Zeiaadini Dashtkhaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3244 5365

Email address

lzeiaadini@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-25, 1396/11/05

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of eight weeks resistance training in land and water on lipid profile change and the blood mononuclear cells PPAR- α and ABCG8 gene expression in middle-aged women after Coronary Artery Bypass Grafting

Public title

Effect of resistance training in cardiac rehabilitation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients were included in the study if they had already had coronary bypass, had a homogeneous level of the disease, and had undergone coronary artery bypass in 3 months ago Patients were relatively fit to carry out the exercises

Exclusion criteria:

Patients were excluded from this study if they had unstable angina, decompensated heart failure,, Myocardial infarction within the last month and problematic ventricular arrhythmias Any other limitations examined by the doctor in period of training

Age

From **43 years** old to **56 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Following a random screening, the participants were divided into control group (CON) (n = 10), the aquatic resistance training group (ART) (n = 10) and dryland resistance training group (DRT) (n = 10). The randomization method will be random numbers. Considering that, numbers 0 -10 for the control group, numbers 10 -20 for dryland resistance training and numbers 20-30 for aquatic resistance training. The researcher starts on one of the numbers and moves in the preset direction, then records the number and specifies the relevant group.

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**

Physical Education and Sport Science Research Center

Street address

No.3 , 5 Miremad Ave

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2017-08-06, 1396/05/15

Ethics committee reference number

IR.SSRI.REC.1396.142

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

Rehabilitation with Aquatic and Dryland Resistance Training on Middle-aged Women's PBMN Cells after Coronary Artery Bypass Grafting

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

PPAR α Gene Expression

Timepoint

At the beginning of the research and 8 weeks after doing intervention

Method of measurement

blood sample

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

ABCG8 gene expression

Timepoint

At the beginning of the research and 8 weeks after doing intervention

Method of measurement

blood sample

2

Description

Lipid profile

Timepoint

At the beginning of the research and 8 weeks after doing intervention

Method of measurement

blood sample

Intervention groups

1

Description

Intervention group: Intervention group 1 will do aquatic resistance training: Aquatic training will take place in a shallow pool (120 cm deep) at a temperature between 28-30°C. Aquatic training exercises (with 60 to 80% of one-repetition maximum for each exercise) will last for 8 weeks (3 sessions per week/ 60 minutes per session) and will include a warm-up (10 minutes), main activity (30-40 minutes) and cooling down (10 minutes). The main activity consists of 3 sets of upper-body dumbbell exercises including: shoulder shrugs, shoulder horizontal extension, shoulder extension with external rotation, and shoulder press with rotation, and lower body exercises with ankle weights including standing leg curls, supported squats, inner and outer thigh abduction, and sliding backward and forward with partial to full ranges of motion, with 8 repetitions during the first four weeks, and 10 repetitions during the fifth to eighth weeks. The training program of each session will differ from other sessions, and be based on the principles of kinesiology, exercise science and hydrodynamics

Category

Rehabilitation

2

Description

Intervention group 2: Dryland resistance training: Dryland training program will include eight weeks of resistance training (3 days a week / 60 minutes per session) and consist of warm-up (10 minutes), main activity (30 to 40 minutes) and cooling down (10 minutes). The main activity will be 8 resistance sessions. It will include machine bench press, seated cable row, inner thigh movements, Lat pull down, Pec deck, outer thigh movements, curl-ups, hyper-extension with 2-3 sets of 12-15 repetitions with 60% of one-repetition maximum. There are 30-second rests between exercises, and 5-minute rests between sets. One-repetition maximum test will repeat at the end of the fourth week to adjust the training protocol to the changes. Based on the results obtained through this test, the training protocol will continue until the end of the eighth week.

Category

Rehabilitation

3

Description

Control group: This group will do no physical activity except everyday life affairs.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Leili Zeiaadini Dashtkhaki

Street address

Safa Ave., Parastar Blvd

City

Kerman

Province

Kerman

Postal code

7618751151

Phone

+98 34 3244 5365

Fax

+98 34 3211 5783

Email

shafahospital@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University of Neyshabur

Full name of responsible person

Mohammad Hossein Hemati

Street address

Pajooheh Blvd

City

Neyshabur

Province

Razavi Khorasan

Postal code

9319797139

Phone

+98 51 4262 1901

Fax

+98 51 4261 5472

Email

Neyshabur@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 of Neyshabur

Proportion provided by this source

100

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

Islamic Azad University of Neyshabur

Full name of responsible person

Leili Zeiaadini Dashtkhaki

Position

PHD student

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

No.5, North Elahieh Ave., Nasr Blvd

City

Kerman

Province

Kerman

Postal code

7618697677

Phone

+98 34 3244 5365

Email

lzeiaadini@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University of Neyshabur

Full name of responsible person

Leili Zeiaadini Dashtkhaki

Position

PHD student

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

No. 5, Elahieh Ave., Nasr Blvd

City

Kerman

Province

Kerman

Postal code

7618697677

Phone

+98 34 3244 5365

Email

lzeiaadini@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University of Neyshabur

Full name of responsible person

Leili Zeiaadini Dashtkhaki

Position

PHD student

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

No. 5, North Elaheih Ave., Nasr Blvd

City

Kerman

Province

Kerman

Postal code

7618697677

Phone

+98 34 3244 5365

Email

lzeiaadini@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

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

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

Title and more details about the data/document

Data of PPAR α and ABCG8 Gene Expression and lipid profile will be report

When the data will become available and for how long

From 18 April 2018

To whom data/document is available

University researchers

Under which criteria data/document could be used

Mention reference

From where data/document is obtainable

lzeiaadini@yahoo.com

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

One week

Comments