Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The Comparison of Eeffect of Aerobic and Combined Exercise Training on Functional Indicators and some cardiovascular risk factors in lower-limb amputee

Protocol summary

Study aim

Comparison of the effect of aerobic and combined exercises on cardiovascular function and some cardiovascular risk factors in male lower limb amputation.

Design

The clinical trial has a control group, with two aerobic groups and a single-strain combination, randomized, on 45 lower limb amputation veterans. Randomization is done by block method and by an assistant outside the research.

Settings and conduct

The experimental groups receive the intervention related to them for 12 weeks at the Isar Hall in Shahrekord. The control group continues their usual activities during 12 weeks. The subjects are blinded to the grouping and the training sessions of the groups are done on different days.

Participants/Inclusion and exclusion criteria

Inclusion criteria included male gender, veterans 50-70%, age group 45-60 years, lower limb amputation, no history of metabolic disease and no smoking. Also, exclusion criteria include infectious diseases such as influenza and covid-19, non-participation in exercises,and use of anti-inflammatory drugs.

Intervention groups

The control group continues their usual activities during 12 weeks. Aerobic group exercises including 12 weeks of exercises will be done in 3 sessions per week. Exercises start in the first week with an intensity of 40% of the maximum heart rate and finally reach 70% of the maximum heart rate in the twelfth week. Combined group exercises include aerobic and resistance exercises for 12 weeks, 3 sessions per week. In the first week, resistance training starts as 2 sets with 8-12 repetitions and with 40% of 1 repetition maximum, and in the twelfth week it reaches 4 sets with 6-8 repetitions and with an intensity of 70% of 1 repetition maximum.

Main outcome variables

C-reactive protein; fasting blood sugar; cholesterol; triglyceride; IL-6; LDL; HDL; ESR V-CAM; LVEF; cardiac muscle hypertrophy; discharge deduction; blood pressure

General information

Reason for update

Acronym

ectc

IRCT registration information

IRCT registration number: **IRCT20210104049939N1**
Registration date: **2023-06-01, 1402/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-01, 1402/03/11**
Update count: **0**

Registration date

2023-06-01, 1402/03/11

Registrant information

Name

MALIHEH HEYDARI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

heidary.m2009@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date
2023-06-02, 1402/03/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Comparison of Eeffect of Aerobic and Combined Exercise Training on Functional Indicators and some cardiovascular risk factors in lower-limb amputee

Public title
Comparison of the effect of 12 weeks of aerobic and combined training based on performance indicators and some other cardiovascular risk factors affected by amputation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Lower extremity amputation veteran Written consent to enter the research Do not have a history of regular sports activities Have no history of advanced metabolic disease Do not smoke Age 45 to 60 years old Being male
Exclusion criteria:
Veterans of upper limb amputation and spinal cord amputation Having a regular sports record Having advanced metabolic disease smoking Infectious diseases such as influenza and covid Failure to participate in training
Age
From **45 years** old to **60 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
After the announcement of the call and examination of the medical files, the candidates are enrolled in the study, and after the examination, based on the criteria of entry and exit from the study, 45 veterans of lower body amputations are selected as a sample. 45 samples are selected through available sampling and randomly divided into one of 3 groups: aerobic training (15 people), combined training (15 people) and control (15 people). Randomization is done by block method and by an assistant outside the research. In this way, the samples are randomized in the form of 3:3:3 blocks in each of the studied groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The subjects are blinded to the grouping and the training sessions of the groups are done on different days.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Najaf Abad branch
Street address
Arghavan Street
City
Najafabad
Province
Isfehan
Postal code
8514143131
Approval date
2020-09-09, 1399/06/19
Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1400.048

Health conditions studied

1

Description of health condition studied
Lower limb amputation veterans
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Improvement of C-reactive protein level in the blood of lower limb amputees due to exercise.due to exercise
Timepoint
24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.
Method of measurement
Blood tests

2

Description
Improving the level of interleukin-6 in the blood of lower

limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood tests

3

Description

Improving the level of v-cam in the blood of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood tests

4

Description

Improving blood ESR levels of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood tests

5

Description

Improving the fasting blood sugar level of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood tests

6

Description

Improvement of systolic blood pressure of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training, the individual's resting blood pressure is taken.

Method of measurement

Manometer

7

Description

Improvement of diastolic blood pressure of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training, the individual's resting blood pressure is taken.

Method of measurement

Manometer

8

Description

Improving the red blood cell sedimentation rate of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood test

9

Description

Lowering blood cholesterol levels of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood test

10

Description

Reducing the level of low-density lipoprotein cholesterol in the blood of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood test

11

Description

Increasing the level of high-density lipoprotein cholesterol in the blood of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after

12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood test

12

Description

Reducing blood triglyceride levels of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood test

13

Description

Improvement of blood alanine aminotransferase levels of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood test

14

Description

Reduction of aspartate aminotransferase levels in the blood of lower limb amputees due to aerobic and combined exercise.

Timepoint

24 hours before the start of the study and 24 hours after 12 weeks of aerobic and combined training at rest and after 10 hours of overnight fasting, the initial blood sample of 10 cc will be taken from the frontal vein of the subjects.

Method of measurement

Blood test

15

Description

Improvement of the end-systolic and diastolic inner diameter of the heart due to aerobic and combined exercise.

Timepoint

24 hours before the start of the first exercise and 24 hours after the last exercise, each subject was asked to lie on his left side after choosing the most suitable image of the heart chambers in the resting state, the end-diastolic and systolic diameters (mm) were measured by one-dimensional method. will be

Method of measurement

Echocardiography device

16

Description

Improvement of left ventricular ejection fraction due to aerobic and combined exercise.

Timepoint

24 hours before the start of the first exercise and 24 hours after the last exercise, each subject was asked to lie on his left side. After selecting the most appropriate image of the heart chambers in the resting state, the variables of the ejection fraction (percentage) are measured by the one-dimensional method.

Method of measurement

Echocardiography device

17

Description

Improving the thickness of the interventricular wall of the heart due to aerobic and combined exercise.

Timepoint

24 hours before the start of the first exercise and 24 hours after the last exercise, each subject was asked to lie on his left side after choosing the most appropriate image of the heart chambers in the resting state, varying the thickness of the interventricular septum (mm) with a one-dimensional measurement method.

Method of measurement

Echocardiography device

18

Description

Improving the thickness of the posterior wall of the left ventricle of the heart as a result of aerobic and combined exercise.

Timepoint

24 hours before the start of the first exercise and 24 hours after the last exercise, each subject was asked to lie on his left side after selecting the most suitable image of the heart chambers in the resting state, varying the thickness of the posterior wall of the left ventricle (mm) with a one-dimensional method. will be measured.

Method of measurement

Echocardiography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aerobic exercise: Aerobic group exercises include 12 weeks of exercises, 3 sessions per week and each session is between 30 and 50 minutes and with increasing load. Each training session consists

of three parts: warm-up, main training body and cool-down. Exercises start in the first week with an intensity of 40% of the maximum heart rate and finally reach 70% of the maximum heart rate in the twelfth week. Maximum heart rate measurement is evaluated using the formula (220-Sen). Also, the assessment of the heart rate of exercise using a polar hourly heart rate monitor.

Category
Prevention

2

Description
Intervention group: Combined exercise: Combined group exercises include aerobic and resistance exercises that are performed for 12 weeks, 3 sessions per week and each session between 30 and 60 minutes, with extra load. Each training session consists of three parts: warm-up, main training body and cool-down. The aerobic part of the exercises is performed in the same way as the aerobic exercise group, but with half the time of the aerobic exercise group. The resistance exercises section includes resistance exercises for the upper body with equipment and free weights for the main and large muscle groups of the upper body (head, forearm, chest, armpit, back of the arm, abdomen). Resistance exercises in the first week in 2 sets with 8-12 repetitions

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Azad University, Najaf Abad branch

Full name of responsible person
Maliheh Heydari

Street address
Najafabad branch, Islamic Azad University, Daneshgah Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Najaf Abad Islamic Azad University

Full name of responsible person
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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
Najaf Abad Islamic Azad University

Proportion provided by this source
5

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
Najafabad Azad University

Full name of responsible person
Maliheh Heydari

Position
Teacher

Latest degree
Master

Other areas of specialty/work
Exercise Cardiovascular Physiology and Respiration

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Person responsible for scientific inquiries

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Person responsible for updating data

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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