

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Comparison of Effect 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

etc

##### 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

+98 38 3337 6061

##### 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 Effect 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**

Isfahan

**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

**City**

Najaf Abad

**Province**

Isfahan

**Postal code**

851414433131

**Phone**

+98 31 4229 1111

**Fax**

+98 31 4229 1016

**Email**

ict@iaun.ac.ir

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

Najaf Abad Islamic Azad University

**Full name of responsible person**

dr. Mehdi Rafiei

**Street address**

Najafabad branch, Islamic Azad University,  
Daneshgah Boulevard

**City**

Najaf Abad

**Province**

Isfahan

**Postal code**

85141433131

**Phone**

+98 31 4229 2305

**Email**

info @ iaun.ac.ir

**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

**Street address**

Isfahan, Najaf Abad, University Boulevard, Najaf Abad  
Azad University

**City**

Najaf Abad

**Province**

Isfahan

**Postal code**

8514143131101

**Phone**

+98 31 4229 2929

**Email**

info @ iaun.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University, Najaf Abad branch

**Full name of responsible person**

Maliheh Heydari

**Position**

Teacher

**Latest degree**

Master

**Other areas of specialty/work**

Cardiovascular physiology

**Street address**

Najafabad branch, Islamic Azad University,  
Daneshgah Boulevard

**City**

Najaf Abad

**Province**

Isfahan

**Postal code**

8514143131

**Phone**

+98 31 4229 2929

**Email**

ict@iaun.ac.ir

## Person responsible for updating data

### 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**

Cardiovascular physiology

**Street address**

Najafabad branch, Islamic Azad University,  
Daneshgah Boulevard

**City**

Najaf Abad

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8514143131

**Phone**

+98 31 4229 2929

**Email**

info @ iaun.ac.ir

## 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