

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 2026

### Investigating the Effect of 8 weeks of combined, intermittent, and continuous aerobic training on lung volumes and capacities and indicators of respiratory pulmonary necrosis and performance of military personnel in a cold climate

#### Protocol summary

##### Study aim

Investigating the effect of the long duration of complex training, continuous and interval aerobic on performance and some necrosis indexes and capacities of the pulmonary system of military personnel in a cold and mountainous climate

##### Design

A clinical trial with randomized parallel groups of 40 participants will run from March 11 to April 21, 2022.

##### Settings and conduct

High-intensity intermittent aerobic exercise group, moderate-intensity continuous aerobic exercise group, moderate-intensity combined exercise group will train for eight weeks and three sessions per week. The control group will be community-based and without practice. All measurements and exercises will be measured in the Ashura Division of Tabriz.

##### Participants/Inclusion and exclusion criteria

Conditions for participation in the study: no regular exercise, no smoking, no history of cardiovascular disease, blood, liver, respiratory diseases, no use of anti-inflammatory drugs such as bronchodilators (beta-receptor agonists) Like salbutamol, no anti-allergy, and no non-steroidal analgesics.

##### Intervention groups

High intensity intermittent aerobic exercise group, moderate intensity continuous aerobic exercise group, moderate intensity combined (resistance and plyometric and control group

##### Main outcome variables

Pulmonary capacity, fitness level, indicators of respiratory necrosis (Clara protein and surfactant D).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210801052049N1**

Registration date: **2022-02-07, 1400/11/18**

Registration timing: **prospective**

Last update: **2022-02-07, 1400/11/18**

Update count: **0**

##### Registration date

2022-02-07, 1400/11/18

##### Registrant information

##### Name

ریاحی سیمین

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8800 4098

##### Email address

riahy\_simin@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-04-21, 1401/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Investigating the Effect of 8 weeks of combined, intermittent, and continuous aerobic training on lung volumes and capacities and indicators of respiratory pulmonary necrosis and performance of military personnel in a cold climate |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Public title</b>                                                                                                                                                                                                                    | Effect of exercise on Respiratory function in cold climates                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Purpose</b>                                                                                                                                                                                                                         | Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                             | Male military personnel working in the city of Tabriz Age between 30 to 45 years                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                             | Not doing regular exercise No smoking No history of cardiovascular disease No blood diseases No liver disease No respiratory diseases Do not take anti inflammatory drugs and bronchodilators (beta-receptor agonists) such as salbutamol and nonsteroidal analgesics.                                                                                                                                                                                                  |
| <b>Age</b>                                                                                                                                                                                                                             | From <b>30 years</b> old to <b>45 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Gender</b>                                                                                                                                                                                                                          | Male                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Phase</b>                                                                                                                                                                                                                           | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Groups that have been masked</b>                                                                                                                                                                                                    | No information                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Sample size</b>                                                                                                                                                                                                                     | Target sample size: <b>40</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                          | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Randomization description</b>                                                                                                                                                                                                       | The selection of volunteers is done by announcing in the battalion. For random grouping of volunteers in 4 experimental groups, the names of each individual were written on a piece of paper and placed inside the box, then we take out the papers one by one. The first 10 names are assigned to the combined exercise group, the second 10 to the intermittent aerobic, the third 10 to the continuous aerobic exercise group, and the last 10 to the control group |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                                               | Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Blinding description</b>                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Placebo</b>                                                                                                                                                                                                                         | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Assignment</b>                                                                                                                                                                                                                      | Single                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Other design features</b>                                                                                                                                                                                                           | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Secondary Ids</b>                                                                                                                                                                                                                   | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Ethics committees</b>                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Ethics committee</b>                                                                                                                                                                                                                | <b>Name of ethics committee</b><br>Ethics Committee of Army University of Medical Sciences<br><b>Street address</b><br>Iran ,Tehran, West Fatemi street<br><b>City</b><br>Tehran<br><b>Province</b><br>Tehran<br><b>Postal code</b><br>1411718541<br><b>Approval date</b><br>2021-07-26, 1400/05/04<br><b>Ethics committee reference number</b><br>IR.AJAUMS.REC.1400.089                                                                                               |
| <b>Health conditions studied</b>                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Description of health condition studied</b>                                                                                                                                                                                         | The subject is not the disease                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>ICD-10 code</b>                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>ICD-10 code description</b>                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Primary outcomes</b>                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                                                                                                                                                                                                                     | Pulmonary capacities                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Timepoint</b>                                                                                                                                                                                                                       | Before training and 48 hours after the last training session                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Method of measurement</b>                                                                                                                                                                                                           | Spirometer                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b><u>2</u></b>                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                                                                                                                                                                                                                     | Clara 16 protein in serum                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Timepoint</b>                                                                                                                                                                                                                       | Before training and 48 hours after the last training session                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Method of measurement</b>                                                                                                                                                                                                           | Eliza                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b><u>3</u></b>                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                                                                                                                                                                                                                     | Surfactant D protein in serum                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Timepoint</b>                                                                                                                                                                                                                       | Before initiation of training and 48 hours after the last training session                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Method of measurement</b>                                                                                                                                                                                                           | Eliza                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b><u>4</u></b>                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                                                                                                                                                                                                                     | Cardiovascular fitness                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Timepoint</b>                                                                                                                                                                                                                       | Before initiation of training and 48 hours after the last                                                                                                                                                                                                                                                                                                                                                                                                               |

training session  
**Method of measurement**  
Measurement the time required to run 3000 meters

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: They do moderate intensity combined training (plyometric and resistance) is performed for 1 hour, 3 days a week for 8 weeks

#### Category

Lifestyle

### 2

#### Description

Intervention group 2: Perform moderate intensity, continuous aerobic exercise for 1 hour a day, 3 days a week for 8 weeks

#### Category

Lifestyle

### 3

#### Description

Intervention group 3: Perform moderate intensity, intermittent aerobic exercise for 1 hour a day, 3 days a week for 8 weeks

#### Category

Lifestyle

### 4

#### Description

Control group: They do not exercise

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Lashkar Ashura of Tabriz

##### Full name of responsible person

Simin Riahy

##### Street address

Kasaei freeway

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

14378350959

##### Phone

+98 21 4382 2360

#### Email

Riahy\_simin@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Mojtaba Yousefi Zashk

##### Street address

West Fatemi street

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

##### Phone

+98 21 4382 2360

##### Email

Riahy\_simin@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Artesh University of Medical Sciences

#### Proportion provided by this source

100

#### 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

Artesh University of Medical Sciences

##### Full name of responsible person

Simin Riahy

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Sport Medicine

##### Street address

West Fatemi Street

##### City

Tehran

##### Province

Tehran

**Postal code**  
1411718541  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Simin Riahy  
**Position**  
Assistant Professor  
**Latest degree**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Simin Riahy  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
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**Street address**  
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**Postal code**  
1411718541  
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Riahy\_simin@yahoo.com

## 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

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is 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

The best training protocol in cold and mountainous weather

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

About 6 months

### To whom data/document is available

All researchers

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

To improve physical activity in cold weather

### From where data/document is obtainable

Article

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

Search electronic resources

### Comments