Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effects Type of Exercise on Ventilatory Efficiency in 11-16 Years Healthy Individuals: A Randomized Clinical Trial

Protocol summary

Study aim

investigate the impact of treadmill and cycle ergometer exercise tests on ventilatory outcomes in healthy adolescents

Design

Subjects attend to lab in three sessions. In first session, resting oxygen consumption, height, weight and anthropometric characteristics were measure, thereafter; they were made familiar with protocols and instruments. In the second and third sessions, for measuring VO2max, the subjects perform treadmill and ergometer protocols in a counterbalance manner so that the first half perform ergometer then cycle protocol and the second half perform vice versa. Two protocols were separated by 4-6 days. All tests were administrated at 10-12 am in 21±1ºC. To determine VO2max, ramp protocol was used.

Settings and conduct

All tests will be held at Shahid Beheshti University. Maximal treadmill exercise test will be perform on a motor driven, electronically controlled treadmill Techno Gym Med (Italy). The main treadmill protocol implemented with a slope of 1 percent. The initial speed was 30% of the final speed computed in the pilot study, and to increase the exercise workload by each minute, we use the final speed minus the initial speed, divided by 10. Maximal exercise test performe on a motor driven, electronically controlled cycle ergometer Monark-839 (Sweden). The protocol of this test start with an initial strength of 30% of the maximum resistance where VO2 max could be achieve (Based on the results of pilot study). Pedaling between 40 and 60 rounds per minute.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: , age 11-16 years old, healthy
Exclusion Criteria: Use medication or supplements or any illness

Intervention groups

The test of VO2 using a treadmill and cycle to evaluate respiratory efficiency in two types of exercise.

Main outcome variables

Time ؛ Heart rate ؛ Ventilatory efficiency index ؛ Minute Ventilation؛ End-tidal carbon dioxide pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220129053867N1**
Registration date: **2022-03-02, 1400/12/11**
Registration timing: **prospective**

Last update: **2022-03-02, 1400/12/11**
Update count: **0**

Registration date

2022-03-02, 1400/12/11

Registrant information

Name

Rostam Alizadeh

Name of organization / entity

Ilam university

Country

Iran (Islamic Republic of)

Phone

+98 84 5924 1463

Email address

r.alizadeh@ilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-05-10, 1401/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects Type of Exercise on Ventilatory Efficiency in 11-16 Years Healthy Individuals: A Randomized Clinical Trial

Public title

The Effects of Treadmill and Cycle Ergometer on Ventilatory Efficiency in 11-16 Years Healthy Individuals: A Randomized Clinical Trial

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

age 11-16 years old, healthy (with no major pulmonary, cardiovascular, or metabolic diseases, such as diabetes)

Exclusion criteria:

Adolescents who took any medication or dietary supplement was excluded from this study.

Age

From **11 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

More than 1 sample in each individual

Number of samples in each individual: **2**

cycle ergometer and treadmill- counterbalance

Randomization (investigator's opinion)

Randomized

Randomization description

In the second and third sessions, for measuring VO2max, the subjects performe treadmill and ergometer protocols in a counterbalance manner so that the first half performed ergometer then cycle protocol and the second half performed vice versa. Two protocols were separate by 5-7 days.

Blinding (investigator's opinion)

Double blinded

Blinding description

Subjects randomly select the type of exercise, the clinical caregiver, the outcome evaluator, and the data analyzer are actually blind.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ilam university of medical sciences

Street address

Ilam University of Medical Sciences, Pajoohesh Blvd, Ilam

City

ILAM

Province

Ilam

Postal code

6939177143

Approval date

2019-04-29, 1398/02/09

Ethics committee reference number

IR.MEDILAM.REC.1398.010

Health conditions studied

1

Description of health condition studied

ventilatory efficiency (VE/VCO2)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Gas exchange measures (MetaLyzer3B-R2- Cortex Germany) were obtained VE/VCO2 breath by breath during the test

Timepoint

All data were reported at two time points: 1) Anaerobic Threshold V-Slop Method (AT), 2) PEAK.

Method of measurement

Gas exchange measures (MetaLyzer3B-R2- Cortex Germany) were obtained breath by breath during the test.

2

Description

Gas exchange measures (MetaLyzer3B-R2- Cortex Germany) were obtained VE breath by breath during the test

Timepoint

All data were reported at two time points: 1) Anaerobic Threshold V-Slop Method (AT), 2) PEAK.

Method of measurement

Gas exchange measures (MetaLyzer3B-R2- Cortex

Germany) were obtained breath by breath during the test.

3

Description
Gas exchange measures (MetaLyzer3B-R2- Cortex Germany) were obtained PetCO2 breath by breath during the test
Timepoint
All data were reported at two time points: 1) Anaerobic Threshold V-Slop Method (AT), 2) PEAK.
Method of measurement
Gas exchange measures (MetaLyzer3B-R2- Cortex Germany) were obtained breath by breath during the test.

4

Description
Gas exchange measures (MetaLyzer3B-R2- Cortex Germany) were obtained VD/VT breath by breath during the test
Timepoint
All data were reported at two time points: 1) Anaerobic Threshold V-Slop Method (AT), 2) PEAK.
Method of measurement
Gas exchange measures (MetaLyzer3B-R2- Cortex Germany) were obtained breath by breath during the test.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Maximal treadmill exercise test will be perform on a motor driven, electronically controlled treadmill Techno Gym Med (Italy). The main treadmill protocol implemented with a slope of 1 percent. The initial speed was 30% of the final speed computed in the pilot study, and to increase the exercise workload by each minute, we use the final speed minus the initial speed, divided by 10.
Category
Diagnosis

2

Description
Intervention group 2: Maximal exercise test performe on a motor driven, electronically controlled cycle ergometer Monark-839 (Sweden). The protocol of this test start with an initial strength of 30% of the maximum resistance where VO2 max could be achieve (Based on the results of pilot study). Pedaling between 40 and 60 rounds per minute.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti University
Full name of responsible person
Rostam Alizadeh
Street address
Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University
Full name of responsible person
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Street address
Ilam University, Pazhoohesh Blvd, Ilam, Ilam.
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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
Ilam University
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
Ilam University

Full name of responsible person
Rostam Alizadeh

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
6 months after publish the results

To whom data/document is available
all

Under which criteria data/document could be used
Use in scientific research by citing the source

From where data/document is obtainable
email

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

Comments