

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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±1°C. 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

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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

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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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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

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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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