Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of 12 weeks of aerobic exercise training on sex hormones and blood markers of airway inflammation in mid luteal phase of asthmatics women

Protocol summary

Summary

The aim of the present study was to investigate the effect of 12 weeks of aerobic exercise training on sex hormones and blood markers of airway inflammation in mid-luteal phase of asthmatics women. 24 women with mild to moderate asthma and regular menstrual cycles were selected and divided into two groups including experimental (n=13) and control (n=11) groups. The experimental group performed aerobic exercise training, and the control group remained inactive. The exercise program lasted for 12 weeks, three sessions a week. Each training session consisted of 15 minutes warm up, 30-minute walk on the treadmill with 60-80% of patients' maximum heart rate and 15 minutes of breathing exercises and cool-down. To reduce problems such as exercise- induced asthma during exercise, American college sport medicine guidelines were used. Before and 24 hours after the last training session, body mass index, VO2peak and blood inflammatory markers such as immunoglobulin E, Eosinophil%, IL-4, IL-5 and IL-13 and also spirometry were measured

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052328028N1**
Registration date: **2017-01-05, 1395/10/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-05, 1395/10/16

Registrant information

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Name of organization / entity

Azarbaijan Shahid Madani University

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Urmia University of Medical Sciences and Researcher

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-09-05, 1395/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 12 weeks of aerobic exercise training on sex hormones and blood markers of airway inflammation in mid luteal phase of asthmatics women

Public title

Effect of aerobic exercise training on inflammatory markers and sex hormones in asthmatic women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: mild to moderate asthma; inactive; regular menstrual cycle and Exclusion criteria: menstrual

disorders; smoking; cardiovascular diseases; other pulmonary diseases

Age
From **25 years** old to **42 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences and Health Service, Next Emergency Center, Resalat Blvd

City
Urmia

Postal code
57147833734

Approval date
2016-04-30, 1395/02/11

Ethics committee reference number
ir.umsu.rec.1395.81

Health conditions studied

1

Description of health condition studied
Asthma

ICD-10 code
J45

ICD-10 code description
Asthma

Primary outcomes

1

Description
Eosinophil%

Timepoint
At baseline and after 3 month exercise training

Method of measurement
Blood collection, CBC-PBS

2

Description
IgE

Timepoint
at baseline and after 3 month exercise training

Method of measurement
Blood collection, immunoassay system (Siemens,USA)

3

Description
IL-4,IL-5,IL-13

Timepoint
At baseline and after 3 month exercise training

Method of measurement
Blood collection, sandwich ELISA kits (R&D, Minneapolis, MN)

4

Description
Estrogen

Timepoint
At baseline and after 12 weeks exercise training

Method of measurement
Blood collection, Inestrument Chemiluminescense Liaison(Diasorin)-Germany

5

Description
Progesterone

Timepoint
At baseline and after tree mounth exercise training

Method of measurement
Blood collection, Chemiluminescence Liaison(Diasorin)-Germany

Secondary outcomes

1

Description
Body Mass Index(BMI)

Timepoint
At baseline and after 3 month exercise training

Method of measurement
Omron Body Composition Monitor, Germany

2

Description
Forced expiratory volume in 1 second
Timepoint
At baseline and after 3 month exercise training
Method of measurement
Spirometer model ST-95 Fukuda. Sanjio. Spiroanalayzer, Japan

3

Description
Vo2peak
Timepoint
At baseline and after 3 month exercise training
Method of measurement
Modified Astrand Treadmill test

Intervention groups

1

Description
Intervention : participating in aerobic training in 12 weeks, 3 times a week, 60 minutes each session.
Category
Lifestyle

2

Description
Control: no intervention for control group.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Sahand Clinic
Full name of responsible person
Mahdia Gholamnejad
Street address
Sahand Clinic, Varzesh Ave, Urmia, Iran
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, University of Urmia
Full name of responsible person
Maghsud Solimanpur
Street address
Faculty of Engineering, Urmia University, Urmia, Iran
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Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, University of Urmia
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty