

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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, VO<sub>2</sub>peak 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

Name

Azam Zarneshan

##### Name of organization / entity

Azarbaijan Shahid Madani University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3432 7505

##### Email address

zarneshan@azaruniv.ac.ir

##### 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, Instrument Chemiluminescence Liaison(Diasorin)-Germany

### 5

#### Description

Progesterone

#### Timepoint

At baseline and after tree month 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. Spiroanalyzer, 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

##### **City**

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**

##### **Name of organization / entity**

Azerbaijan Shahid Madani University

##### **Full name of responsible person**

Azam Zarneshan

##### **Position**

Ph.D. Student In Exercise Physiology Of Urmia University / Faculty Member Of Azerbaijan Shahid Mada

##### **Other areas of specialty/work**

##### **Street address**

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Azarbaijan Shahid Madani University

**Full name of responsible person**

Azam Zarneshan

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**City**

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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*