

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Anti-atherosclerosis effects of 12 weeks high intensity interval and aerobic training on serum levels salusin- $\alpha$ and - $\beta$ , nitric oxide, inflammatory markers and lipid profile in overweight and obese childrens

#### Protocol summary

##### Study aim

Anti-atherosclerosis effects of 12 weeks high intensity interval and aerobic training on serum levels salusin- $\alpha$  and - $\beta$ , nitric oxide, inflammatory markers and lipid profile in overweight and obese childrens

##### Design

At first, considering the importance of the subject, obtaining the necessary permits from the department of education and the necessary coordination was randomly accessed by 20 schools from city-wide schools and surveying the inclusion criteria of 120 students (9-12 years). Subjects were invited to participate in the study, then a consent form, a medical history questionnaire and a physician referral form were presented to the subjects. Forty-five of them, with the consent of their parents and the student, participated in the study.

##### Settings and conduct

Subjects were randomly assigned to a HIIT group (n= 15) that trained at %100-110 MAS; an aerobic group (n= 15) who trained at %40-70 HRR and a control group without exercise. Exercise groups (aerobic and HIIT) trained 3 sessions per week on non-consecutive days according to their training protocols for 12 weeks. Training sessions included three parts: Standard warm-up section, main body of exercise and cooling part at end of training session.

##### Participants/Inclusion and exclusion criteria

Children 9 to 12 years old

##### Intervention groups

Three groups of high intensity training, aerobic exercise and control

##### Main outcome variables

Salusin- $\alpha$ ; Salusin- $\beta$ ; Nitric oxide; Interleukin-6 and Lipid profile

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200116046154N1**

Registration date: **2020-02-11, 1398/11/22**

Registration timing: **retrospective**

Last update: **2020-02-11, 1398/11/22**

Update count: **0**

##### Registration date

2020-02-11, 1398/11/22

##### Registrant information

##### Name

Alireza Paahoo

##### Name of organization / entity

Razi university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 4522 9563

##### Email address

paahoo.alireza@razi.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-08-23, 1397/06/01

##### Actual recruitment start date

2018-05-22, 1397/03/01

##### Actual recruitment end date

2018-08-23, 1397/06/01

##### Trial completion date

2018-08-23, 1397/06/01

### Scientific title

Anti-atherosclerosis effects of 12 weeks high intensity interval and aerobic training on serum levels salusin- $\alpha$  and - $\beta$ , nitric oxide, inflammatory markers and lipid profile in overweight and obese childrens

### Public title

Anti-atherosclerosis effects of 12 weeks high intensity interval and aerobic training on serum levels salusin- $\alpha$  and - $\beta$ , nitric oxide, inflammatory markers and lipid profile in overweight and obese childrens

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Ages 9 to 12 years Body mass index between 19.1-26.2 No drug treatment NO chronic diseases such as diabetes, metabolic syndrome (systolic blood pressure 130 mm Hg or diastolic blood pressure 85 mm Hg, waist circumference greater than 102 cm and fasting glucose 110 mm Hg), hormone, orthopedic Not participating in any regular training program (except for exercise ring) within 6 months prior to entering the study The subjects must be boys

#### Exclusion criteria:

Voluntary withdrawal by participants for any reason. Acute infectious diseases such as influenza during research. Two consecutive absentee sessions and three non-consecutive sessions during the time of the research run. Acute Injury Due to Practice During Research.

### Age

From **9 years** old to **12 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **45**

Actual sample size reached: **45**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Forty-five subjects from 20 schools participated in the study and were randomly divided into 3 groups of HIIT, aerobic and control groups. Randomization of the study groups was performed using simple or unlimited randomization by using dice such that the numbers 1 and 2 for the first group, 3 and 4 for the second group, and 5 and 6 for the third group were considered. Were taken.

### 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

Kermanshah University of Medical Sciences

##### Street address

Shahid Beheshti Boulevard

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

#### Approval date

2019-01-30, 1397/11/10

#### Ethics committee reference number

IR.KUMS.REC.1397.936

## Health conditions studied

### 1

#### Description of health condition studied

Anti-Atherosclerosis Effects of exercise

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

salusin- $\alpha$

#### Timepoint

Pre and Post test

#### Method of measurement

Blood sampling and laboratory kit

### 2

#### Description

salusin- $\beta$

#### Timepoint

Pre and Post test

#### Method of measurement

Blood sampling and laboratory kit

### 3

#### Description

Nitric oxide

#### Timepoint

Pre and Post test

#### Method of measurement

Blood sampling and laboratory kit

## 4

### **Description**

Interleukin-6

### **Timepoint**

Pre and Post test

### **Method of measurement**

Blood sampling and laboratory kit

## 5

### **Description**

C-reactive protein

### **Timepoint**

Pre and Post test

### **Method of measurement**

Blood sampling and laboratory kit

## 6

### **Description**

Lipid profile

### **Timepoint**

Pre and Post test

### **Method of measurement**

Blood sampling and laboratory kit

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Intervention group: A briefing was held to familiarize children with the exercise protocol and to measure anthropometric parameters such as height, weight, body mass index, waist and hip circumference, subcutaneous fat thickness. Twenty-four hours after the briefing session, a field test for children or a shuttle ride test was performed to measure aerobic fitness and maximal aerobic speed. 72 hours after the shuttle test, the first blood sample was taken at 7:30 am to 8 am after 12 hours in fasting HIIT subjects to measure the components of the study. 48 hours after blood sampling in the HIIT subjects according to their intended severity and their specific distances obtained by calculating their maximum aerobic velocity and determined by the cones for each subject separately, 100 to 120% of maximal aerobic speed were trained 3 times a week for 12 weeks.

### **Category**

N/A

## 2

### **Description**

Intervention group: A briefing was held to familiarize children with the exercise protocol and to measure anthropometric parameters such as height, weight, body mass index, waist and hip circumference, subcutaneous fat thickness. Twenty-four hours after the briefing

session, a field test for children or a shuttle run test was performed to measure aerobic fitness and maximal aerobic speed. 72 hours after the shuttle test, the first blood samples were taken at 7:30 am to 8 am after 12 hours of fasting in the aerobic exercise group to measure the components of the study. 48 hours after blood sampling, aerobic group subjects were also warmed up and stretched according to the intensity and duration of the study, based on 40-70% of heart rate reserve 3 sessions per week. They practiced for 12 weeks.

### **Category**

N/A

## 3

### **Description**

Control group: A briefing was held to familiarize children with the exercise protocol and to measure anthropometric parameters such as height, weight, body mass index, waist and hip circumference, subcutaneous fat thickness. 72 hours after the briefing, the first blood sample was taken at 7:30 am to 8 am after 12 hours in the fasting state of the control group to measure the research components. The control group continued their normal routine throughout the 12 weeks of the study, and was advised not to engage in any organized exercise.

### **Category**

N/A

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Razi University

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

Alireza Paahoo

#### **Street address**

Shahid Nazari St.

#### **City**

Eslamabad-e Gharb

#### **Province**

Kermanshah

#### **Postal code**

6761935817

#### **Phone**

+98 83 4522 9563

#### **Email**

alirezapaaho@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

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

Razi University

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

Vahid Tadibi

#### **Street address**

Room no.67, Faculty of Physical Education and Sport Sciences, Razi University, Zakariya Razi Blvd.

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**Province**

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**Postal code**

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**Phone**

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**Email**

vtadibi@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Razi University

**Proportion provided by this source**

50

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**2****Sponsor****Name of organization / entity**

Razi University

**Full name of responsible person**

Farzad Veysi

**Street address**

Zakariya Razi Blvd, Razi University.

**City**

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**Province**

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**Phone**

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**Email**

veysi@razi.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Razi University

**Proportion provided by this source**

50

**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**

Razi University

**Full name of responsible person**

Vahid Tadibi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise physiology

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Razi University

**Full name of responsible person**

Vahid Tadibi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise physiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Razi University

**Full name of responsible person**

Alireza Paahoo

**Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise physiology

**Street address**

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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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The individual data of the study participants are shared after unidentifiable individuals are identified

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

Two month

**To whom data/document is available**

Researchers

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

For the sake of transparency and researcher satisfaction

**From where data/document is obtainable**

Alireza Paahoo

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

Request and send to researcher

**Comments**