Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Anti-atherosclerosis effects of 12 weeks high intensity interval and aerobic training on serum levels salusin-α and -β, 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-α and -β, 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-α; Salusin-β; 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

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Email address

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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-α and -β, 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-α and -β, 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-α

Timepoint
Pre and Post test

Method of measurement
Blood sampling and laboratory kit

2

Description
salusin-β

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
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Shahid Nazari St.
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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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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.

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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
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

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Person responsible for scientific inquiries

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Full name of responsible person
Vahid Tadibi

Position
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Latest degree
Ph.D.

Other areas of specialty/work
Exercise physiology

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Person responsible for updating data

Contact

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Position
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Latest degree
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Other areas of specialty/work
Exercise 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
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