

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The comparison between the effect of aerobic exercise and no exercise on salivary immunoglobulin a, cortisol, body composition and physical fitness in children with allergic rhinitis .

Protocol summary

Summary

Aim: The study aims to compare the effect of aerobic exercise and no exercise on salivary immunoglobulin A, cortisol, body composition and physical fitness in children with allergic rhinitis. Design: This is a controlled clinical trial. Setting and conduct: 19 children with allergic rhinitis aged between 6-7 years will tend voluntarily in this study and will be randomly divided into experimental and control groups. Major inclusion and exclusion criteria: The inclusion criteria are 6-7 years of age; and allergic rhinitis. The exclusion criteria is no willing to attend in this study. Intervention: subjects in the experimental group will participate in aerobic exercise program for 6 weeks. The control group will not attend in any exercise program. Main outcome measures: The levels of immunoglobulin A and cortisol physical fitness test (sit and reach, 30 meter sprint test, vertical jump and 4 x 10 m shuttle run test) and body composition will be measured.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015061422498N1**

Registration date: **2015-08-12, 1394/05/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-12, 1394/05/21

Registrant information

Name

Ramin Shabani

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 13 3375 2715

Email address

shabani@iaurasht.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-06-26, 1394/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between the effect of aerobic exercise and no exercise on salivary immunoglobulin A, cortisol, body composition and physical fitness in children with allergic rhinitis .

Public title

The comparison between the effect of aerobic exercise and no exercise on salivary immunoglobulin A, cortisol, body composition and physical fitness in children with allergic rhinitis.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Children Aged 6-7 years old; and

Allergic Rhinitis Exclusion Criteria: No Willing to Attend .

Age

From **6 years** old to **7 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **19**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Randomization by Closed Pockets

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Human Studies Review Committee at Islamic Azad
University of Rasht

Street address

Lakan Boulevard

City

Rasht

Postal code

3516-41335

Approval date

2015-01-31, 1393/11/11

Ethics committee reference number

11721404822004

Health conditions studied

1

Description of health condition studied

Allergic Rhinitic

ICD-10 code

J30

ICD-10 code description

Vasomotor and allergic rhinitis

Primary outcomes

1

Description

cortisol level

Timepoint

after six weeks of exercise training

Method of measurement

microplate Enzyme linked Immunosorbent Assay

2

Description

Immunoglobulin A level

Timepoint

after six weeks of exercise training

Method of measurement

microplate Enzyme linked Immunosorbent Assay

Secondary outcomes

1

Description

Body Composition

Timepoint

6 weeks after Exercise Training

Method of measurement

BMI , WHR and Weight

2

Description

Fitness Indicators

Timepoint

After Six Weeks Of Exercise Training

Method of measurement

Fitness Test : Flexibility Test , 30 Meter Sprint, Sarjent
Test And 4 In 10 Meters Agility

Intervention groups

1

Description

Intervention group 1: 6 Weeks Aerobic Exercise with 60
Minutes Lenght, 3 Sessions per Week including 10
Minutes Warm up, 10 Minutes Cool down and 40 minutes
Aerobic Exercise with Moderate Intensity

Category

Lifestyle

2

Description

control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sarafraz Elementary School

Full name of responsible person

Shiva Nemati

Street address

Lakan BVL

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University of Rasht

Full name of responsible person

Ramin Shabani

Street address

Lakan BVL

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Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University of Rasht

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

Islamic Azad university of Rasht

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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