

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of 12 weeks of combined exercise and detraining on levels of adipokines, cytokines, puberty symptoms and mental health in overweight and obese girls with central precocious puberty

Protocol summary

Study aim

Evaluation of changes in the levels of adipokines (adiponectin, resistin, ghrelin, leptin) and cytokines (tumor necrosis factor-alpha and C-reactive protein) and signs of puberty (bone age, ovarian and uterine size, levels of luteinizing hormone and follicle-stimulating hormone) and mental health after 12 weeks of combined exercise and 4 weeks of detraining

Design

Clinical trial with control group, parallel, non-blind, randomised, phase 1 groups on 30 patients

Settings and conduct

The 12-weeks intervention in exercise group involved a physical activity program with 3 60-min sessions/week consisted of 30 min of aerobic exercise with an intensity of 55% to 65% of individual maximal cardio-respiratory fitness followed by 20 min of strengthening exercises and 10 min of stretching and cool-down Which is done by two experienced coaches in the sports hall of the civil town of Hamedan. Sampling is done before the start of the exercise protocol, after 12 weeks of exercise and after 4 weeks of detraining.

Participants/Inclusion and exclusion criteria

The inclusion criteria: 1. Girls with central precocious puberty; 2. Having a BMI higher than 19; 3. The age range of 7 to 9 years; 4. taking about one year before a diagnosis had been made; 5. Being on medication for one year; 6. Being treated with Differlin drug ; 7. Taking medication 1 ml every 28 days. The exclusion criteria: 1. having another illness; 2. taking another medicine; 3. having a special diet; 4. being active in another sport; 5. being connected to drugs.

Intervention groups

intervention and control group

Main outcome variables

adiponectin, resistin, ghrelin, leptin, tumor necrosis factor-alpha, C-reactive protein, bone age, ovarian and

uterine size, luteinizing hormone and follicle-stimulating hormone, mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210525051396N1**

Registration date: **2021-11-12, 1400/08/21**

Registration timing: **retrospective**

Last update: **2021-11-12, 1400/08/21**

Update count: **0**

Registration date

2021-11-12, 1400/08/21

Registrant information

Name

Elnaz Shokri

Name of organization / entity

Bu-Ali Sina university

Country

Iran (Islamic Republic of)

Phone

+98 81 3420 0234

Email address

e.shokri7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2020-05-21, 1399/03/01

Trial completion date

2020-05-21, 1399/03/01

Scientific title

The effect of 12 weeks of combined exercise and detraining on levels of adipokines, cytokines, puberty symptoms and mental health in overweight and obese girls with central precocious puberty

Public title

The effect of combined exercise and detraining on overweight and obese girls with precocious puberty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Girls with central precocious puberty Having a BMI higher than 19 The age range of 7 to 9 years One year has passed since they were diagnosed with precocious puberty Being on medication for one year Being treated with Differlin drug Taking medication 1 ml every 28 days

Exclusion criteria:

having another illness taking another medicine having a special diet being active in another sport being connected to drugs

Age

From **7 years** old to **9 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by block method, the size of blocks is equal to 6 with two members in a ratio of 1: 1. Using the site www.sealedenvelope.com, a random sequence of 6 blocks with two members Control and Treatment is determined, then the sequence of intervention and control groups in different envelopes from number 1 to the sample size is considered. Upon arrival of each eligible volunteer, one of the envelopes is opened and its treatment group is determined.

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**

Research Ethics Committees of Bu Ali Sina University-Hamedan

Street address

No 46, Yas 7 Ave., Azadegan 1 Ave., Madani Town

City

Hamedan

Province

Hamadan

Postal code

6513869143

Approval date

2021-10-13, 1400/07/21

Ethics committee reference number

IR.BASU.REC.1400.038

Health conditions studied**1****Description of health condition studied**

central precocious puberty

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Cytokines

Timepoint

Baseline, 12 weeks, 16 weeks

Method of measurement

Blood sampling and use of laboratory kits

2**Description**

Stimulating hormones Sex hormones (lutein and follicle stimulating)

Timepoint

Baseline, 12 weeks, 16 weeks

Method of measurement

Blood sampling and use of laboratory kits

3**Description**

Signs of puberty (uterine and ovarian size, bone age)

Timepoint

Baseline, 12 weeks, 16 weeks

Method of measurement

Ultrasound and Grolich and Pyle Atlas

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Other

2

Description

Control group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat hospital

Full name of responsible person

Dr. Zahra razavi

Street address

Shahid Motahari Blvd, Resalat Sqe

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+98 81 3264 0030

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+98 81 3262 1515

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besat@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bu-Ali sina university

Full name of responsible person

Ali Heidarian pour

Street address

The four gardens of Martyr Mostafa Ahmadi Roshan

City

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6517838695

Phone

+98 81 3838 1601

Email

IT_Services@basu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bu-Ali sina university

Proportion provided by this source

25

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

Bu-Ali Sina university

Full name of responsible person

Elnaz Shokri

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

From the year 1400

To whom data/document is available

Researchers working in academic and scientific institutions, physicians and people with precocious puberty

Under which criteria data/document could be used

Statistical analysis

From where data/document is obtainable

1- Email to e.shokri7@gmail.com 2- Refer to Bu Ali Sina University, Faculty of Sport Sciences, Iran, Hamedan 3- Call 09368067208

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

After one of the three methods listed, data will be sent to the person.

Comments