Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
City
Hamedan
Province
Hamadan
Postal code
6513869143
Phone
+98 81 3264 0030
Fax
+98 81 3262 1515
Email
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
Hamedan
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Hamadan
Postal code
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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Full name of responsible person

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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