

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of exercise training and detraining on cortisol level and mental health of over weight and obese girls with precocious puberty

Protocol summary

Study aim

Evaluation of changes in weight, body mass index, cortisol level and mental health (anxiety, depression and aggression) after 12 weeks of combined exercise and 4 weeks of detraining

Design

Clinical trial with control group, parallel, non-blind, randomised,

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 and Measurement of questionnaire factors 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; The exclusion criteria: 1. having another illness; 2. Use of any medication other than Differlin ; 3. having a special diet (Vegetarianism,...); 4. being active in another sport.

Intervention groups

1- Intervention group: 22 overweight and obese girls with precocious puberty who receive Differlin every 28 days as an intramuscular injection and perform combined exercise (resistance + aerobic) for 12 weeks 2 - Control group: 22 overweight and obese girls with precocious puberty who receive Differlin only intramuscular injection every 28 days

Main outcome variables

Weight, body mass index, cortisol, anxiety, depression, aggression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170411033378N10**

Registration date: **2022-02-27, 1400/12/08**

Registration timing: **prospective**

Last update: **2022-02-27, 1400/12/08**

Update count: **0**

Registration date

2022-02-27, 1400/12/08

Registrant information

Name

Efat Sadeghian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

sadeghian_e@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercise training and detraining on cortisol level and mental health of over weight and obese girls with precocious puberty

Public title

The effects of exercise on mental health of obese girls with precocious puberty

Purpose

Supportive

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 treated with Differlin drug Taking medication 1 ml every 28 days

Exclusion criteria:

having another illness taking another medicine having a special diet (Vegetarianism, ...) being active in another sport being connected to drugs

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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 Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., in front of the People's Park of Hamadan University of Medical Sciences and Health Services

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2022-01-26, 1400/11/06

Ethics committee reference number

IR.UMSHA.REC.1400.883

Health conditions studied

1

Description of health condition studied

Precocious puberty

ICD-10 code

E30.1

ICD-10 code description

Precocious puberty

Primary outcomes

1

Description

Cortisol

Timepoint

Baseline, 12 weeks, 16 weeks

Method of measurement

Blood sampling and use of laboratory kits Elisa method

2

Description

Weight and body mass index

Timepoint

Baseline, 12 weeks, 16 weeks

Method of measurement

Digital scale, standard height meter

3

Description

anxiety

Timepoint

Baseline, 12 weeks, 16 weeks

Method of measurement

Spence Children Anxiety Scale

4

Description

depression

Timepoint

Baseline, 12 weeks, 16 weeks

Method of measurement

Self-rating Depression Scale

5

Description

aggression

Timepoint

Baseline, 12 weeks, 16 weeks

Method of measurement

Nelson Child Aggression Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention used is a combination training protocol (aerobic + resistance) for 12 weeks, 3 sessions per week and each session will be 60 minutes of aerobic + resistance training in which 30 minutes of aerobic exercise including walking, running, ball games With 55 to 65% of heart rate and 20 minutes of resistance training in the arms, legs and trunk in 2 or 3 sets of 10 to 15, which will be done through body weight or elastic bands, and at the end of each session, cool down for 10 minutes and we will return to the original state.

Category

Rehabilitation

2

Description

Control group: Does not receive intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Sciences

Full name of responsible person

Dr.Efat Sadeghian

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Shahid Fahmideh Blvd, Hamadan University of Medical Sciences

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sadeghianefat@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Efat Sadeghian

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Grant name

Grant code / Reference number

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

No

Title of funding source

Hamadan University of Medical Sciences

Proportion provided by this source

100

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

Hamedan University of Medical Sciences

Full name of responsible person

Efat Sadeghian

Position

Associate professo

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

IPD briefly describe what specific participant data sets
are to be shared

When the data will become available and for how long

starting in July 2022

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

people working in academic institutions

From where data/document is obtainable

Efat Sadeghian via Email: sadeghianefat@gmail.com

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

via Email: sadeghianefat@gmail.com

Comments