

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the effect of 12 weeks of plyometric and HICT training on serum levels of FGF23, KLOTHO, and Some markers related to bone metabolism in adolescent boy

Protocol summary

Study aim

comparing the effect of 12 weeks of plyometric and HICT exercises on FGF23, α Klotho, GH/IGF-1, calcitriol, serum phosphate, serum calcium and BMD and BMC and some marker related to bone in male adolescents.

Design

The current research is semi-experimental with a pre-test-post-test design along with a control group, with parallel groups, unblinded, on 66 patients, randomized by a simple lottery method, and in terms of the purpose, it is an applied-fundamental research type.

Settings and conduct

The statistical population of this study is adolescent boys of educational schools in Yazd city, 66 of them are selected based on the study entry criteria and then randomly divided into two experimental groups and one control group.

Participants/Inclusion and exclusion criteria

Written consent of students' parents for participating in this plan; Adolescent boys aged 13-15 years old.
Exclusion criteria: any chronic disease; any drug use; participating in regular sports activities.

Intervention groups

intervention1: Plyometric training group - three days a week - for 12 weeks intervention2: HICT training group - three days a week - for 12 weeks intervention3: The control group does not receive any training.

Main outcome variables

Serum level of fgf23, aklotho, gh/igf-1 and calsitriol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221102056381N1**
Registration date: **2023-06-24, 1402/04/03**

Registration timing: **retrospective**

Last update: **2023-06-24, 1402/04/03**

Update count: **0**

Registration date

2023-06-24, 1402/04/03

Registrant information

Name

reyhane shokoohi

Name of organization / entity

The university of Shahrekord

Country

Iran (Islamic Republic of)

Phone

+98 35 3522 2540

Email address

r.shokoohi2008@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-05-10, 1402/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 12 weeks of plyometric and HICT training on serum levels of FGF23, KLOTHO, and Some markers related to bone metabolism in adolescent boy

Public title

Comparison of the effect of exercise training on bone metabolism in adolescent boy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Male teenagers Aged 13-15 years

Exclusion criteria:

Any type of disease such as anemia, obesity, diabetes, heart disease Using any type of special medicine Participating in regular sports activities in the last 6 months

Age

From **13 years** old to **15 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

To reduce the influence of maturity, and to maximize the balance and homogenization of the groups, 63 selected subjects of this research (selected based on the inclusion criteria) were also examined in terms of biological maturity status. Considering the importance of biological maturity in the present research and with the aim of relatively balanced distribution of the subjects in groups, first we stratified the subjects based on the status of biological maturity and using the age of peak height velocity (aPHV) formula. Random allocation software is also used for randomization. In addition to simple randomization, these random sequence generation softwares are capable of generating a random sequence using the block method, that from each block, three subjects were placed in the control group, three subjects in the intervention group 1, and three subjects in the intervention group 2, so that the number of subjects Each group reached 21 people. The advantage of this method is that the distribution of the subjects is done in a more balanced and favorable manner, and it will not be the case that most of the subjects of one group have a significantly higher biological age than other groups.

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

Ethics Committee of Shahrekord University

Street address

Shahrekord University, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۸۶۳۴۱۴۱

Approval date

2023-04-30, 1402/02/10

Ethics committee reference number

IR.SKU.REC.1402.007

Health conditions studied

1

Description of health condition studied

Bone Density

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum level of FGF23

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

Eliza kit (BioSwamp Company, NY, USA)

2

Description

Serum level of α Klotho

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

Using the ELISA kit

3

Description

Serum level of GH

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

radium kit

4

Description

SERUM LEVEL OF IGF-1

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

DRG IGF-11600 enzyme immunoassay kit

5

Description

BMD

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

Dual-energy X-ray absorptiometry (DEXA)

6

Description

BMC

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

Dual-energy X-ray absorptiometry (DEXA)

Secondary outcomes

1

Description

SERUM LEVEL OF CALSITERIOL

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

ELISA TEST

2

Description

SERUM LEVEL OF PHOSPHATE

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

ELISA TEST

3

Description

SERUM LEVEL OF CALSIUM

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

ELISA TEST

4

Description

serum level of PHEX

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

ELISA TEST

5

Description

serum level of PTH

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

ELISA TEST

6

Description

serum level of vitamin D

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

Elisa test

7

Description

serum level of DMP1

Timepoint

Before and after 12 weeks of plyometric and HICT training

Method of measurement

Elisa test

Intervention groups

1

Description

Intervention group 1: HICT exercise protocol is performed three days a week for 12 weeks. The intensity of the exercises will be gradually increased by using the methods of increasing the training pressure.

Category

Other

2

Description

Intervention group 2: plyometric exercise protocol is performed three days a week for 12 weeks. The intensity of the exercises will be gradually increased by using the methods of increasing the training pressure.

Category

Other

3

Description

Control group: They do not receive any kind of training

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mehdizade School

Full name of responsible person

Masoud Hasanpoor

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Sajjad North Street - Vali Asr Blvd - Yazd town - Yazd Province

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University

Full name of responsible person

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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

Shahrekord University

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

Shahrekord University

Full name of responsible person

Reyhane Shokoohi

Position

Student

Latest degree

Master

Other areas of specialty/work

Exercise physiology

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Person responsible for scientific inquiries

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Associate Professor

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Other areas of specialty/work

Exercise Physiology

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Reyhane Shokoohi

Position

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Latest degree

Master

Other areas of specialty/work

Exercise physiology

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Postal code

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available