

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of a 12-weeks period of elastic band resistance training on some growth and osteogenic factors and its relationship with bone density in elderly osteosarcopenic obese women

Protocol summary

Study aim

The Effect of a 12-Weeks period of elastic band resistance training on Some growth and osteogenic factors and its relationship with bone density in elderly osteosarcopenic obesity women

Design

Clinical trial with control and intervention groups and parallel group design; Randomization with random block method (blocks of size 2) and sealed envelopes. Sample size is estimated equal to 63.

Settings and conduct

This clinical study is in the field of elderly medicine and sports and is an applicable one. Patient sampling will be performed at Kashani hospital and medical clinics and laboratories of the Shahrekord city. The training programs will be provided by the trained sports coach and follow up of the control group will be done at Pars Rehabilitation Center. Each participant will receive a scan of bone density measurement using a dual-energy x-ray absorptiometry (DXA) and a blood sample at the beginning and end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 60 years old; Fat Percent > 32 or Body Mass Index (BMI) > 30; T-Score < -1.0; Hand Grip < 21 kg; Skeletal Muscle Mass Index < 7.26 kg/m²; Having exercise at the same time as the plan, following a weight loss diet, suffering from chronic illnesses or smoking or hormone therapy, or taking medications that may affect bone density, adipose tissue, or the hormonal system.

Intervention groups

Intervention / Exercise group : participants in this group participate in a 12-week elastic band resistance training program consisting of 3 sessions per week and each session takes 45-60 minutes. In order to respect the principle of overload after every 2 weeks, the intensity of exercises using elastic bands of discoloration increases.

The control group: does not participate in any nutrition or exercise program.

Main outcome variables

Serum levels of myostatin, follistatin, insulin-like growth factor-1 (IGF-1), fibroblast growth factor-2 (FGF-2)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190705044101N1**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **retrospective**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Negin kazemipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

2019-07-14, 1398/04/23

Actual recruitment end date

2019-07-22, 1398/04/31

Trial completion date

2019-07-22, 1398/04/31

Scientific title

The effect of a 12-weeks period of elastic band resistance training on some growth and osteogenic factors and its relationship with bone density in elderly osteosarcopenic obese women

Public title

Effect of resistance training on growth and osteogenic factors of elderly women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 60 years Body fat percent over 32% or BMI over 30 T-score less than -1.0 Hand grip less than 21kg Skeletal mass index (SMI) less than %28

Exclusion criteria:

Having parallel physical exercises Following a weight loss diet of more than 5 kg in the last three months Chronic illness such as hypertension, thyroid or kidney problems, diabetes, cancer very severe osteoporosis Hormone therapy or any drug that affects bone density, adipose tissue, or the hormonal system.

Age

From **60 years** old to **80 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Actual sample size reached: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

After completing all initial assessments, subjects were grouped using binary block randomization to balance the number of samples assigned to the exercise and control groups in a 1: 1 ratio. The sealed envelope was also used because of the importance of hiding the random allocation.

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 Sport Sciences Research Institute

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No.3, fifth Alley, Mir Emad Ave, Ostad Motahari street

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Province

Tehran

Postal code

1587958711

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.SSRC.REC.1398.040

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

Osteosarcopenic obesity syndrome

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

postmenopausal osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Age-related osteoporosis without current pathological fracture

Primary outcomes**1****Description**

Myostatin

Timepoint

24 hours before the intervention and 48 hours after the end of the last training session

Method of measurement

Elisa Kit (Pack of 96)

2**Description**

Follistatin

Timepoint

24 hours before the intervention and 48 hours after the end of the last training session

Method of measurement

Elisa Kit (Pack of 96)

3

Description

Insulin-like growth factor 1(IGF-1)

Timepoint

24 hours before the intervention and 48 hours after the end of the last training session

Method of measurement

Elisa Kit (Pack of 96)

4

Description

Fibroblast Growth Factor2(FGF-2)

Timepoint

24 hours before the intervention and 48 hours after the end of the last training session

Method of measurement

Elisa Kit(Pack of 96)

Secondary outcomes

1

Description

Bone Densitometry

Timepoint

One week Before the Intervention and one Week After the Last Training Session

Method of measurement

dual-energy X-ray absorptiometry (DXA)

2

Description

Body Fat Percent

Timepoint

One week Before the Intervention and one Week After the Last Training Session

Method of measurement

Use the Harpernet model calipers

Intervention groups

1

Description

Intervention group: Subjects in This Group Performed an Elastic Band (3 Sessions Per Week, Each Session for Approximately 60 minutes) for 12 Weeks.Practicing Intensity Control is Practiced Using the Targeted Repeat Count (TNRs) and the OMNI Resistance Training Scale.In order to Comply with the Principle of Overload After Every 2 Weeks of Training, The Intensity of Exercise is Increased by Using the Elastic Band Color Change (yellow, red, blue, green, black, silver), Respectively.Participants in This Group Follow Their Past Food Plans.

Category

Treatment - Other

2

Description

Control group: The subjects in This Group do Their Routine Activities within 12 Weeks.Participants in This Group Follow Their Past Food Plans.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashni Hospital

Full name of responsible person

Mohammad Ali Dayani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

No

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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

The University of Shahrekord

Full name of responsible person

Ebrahim Banitalebi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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