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 a12-Weeks period of elastic band resistance training on Some growth and osteogenic factors and its relashioship 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, folistatin, 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)

Phone

+98 61 3622 4545

Email address

kazemi_pour@iaumis.ac.ir

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
Street address
No.3, fifth Alley, Mir Emad Ave, Ostad Motahari street
City
Tehran
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
Street address
Shariati blvd, Parastar avenue
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۶۷۵۸۹۱۵
Phone
+98 38 3226 4825
Email
Kashani@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Mohammad Mansorifar
Street address
No.70, Shahid Gholamali Mazlom alley ,After the governorate, Taleghani Blvd
City
Shoushtar
Province
Khouzestan
Postal code
6451613779
Phone
+98 61 3627 2014
Email
info@iau-shoushtar.ac.ir
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
Street address
Shahrekord University, Rahbar blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۸۶۳۴۱۴۱
Phone
+98 38 3232 4401
Email
banitalebi.e@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
The University of Shahrekord
Full name of responsible person
Dr Mohammad Faramarzi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Physiology
Street address
The University of Shahrekord, Rahbar Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۸۶۳۴۱۴۱
Phone
+98 38 3232 4407
Email
md.faramarzi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Negin Kazemipour
Position
Lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Sport Physiology
Street address
Islamic Azad University Of Masjed Soleyman, Shahid Abbassspoor dam three-road
City
Masjed Soleiman
Province
Khouzestan
Postal code
6491796581
Phone
+98 61 4326 7102
Email
kazemi_pour@iaumis.ac.ir

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