Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Study of Effect of a 24-Weeks Period of Elastic Resistance Band Training on Biomarkers of Osteosarcopenia Obesity in Osteosarcopenic Obese Women

Protocol summary

Study aim
Determining the effect of 24 weeks resistance training with elastic cache on serum sclerostine levels and with elastic cuffs on serum levels of troponin T in elderly women with osteosarcopenic obesity

Design
Randomised, Clinical trial, control and intervention groups

Settings and conduct
This is an applied clinical study in the field of elderly medicine and exercise.Patient sampling is done at Hagar Hospital and in the city's health clinics.Sports exercises and follow up of the control group at Pars Rehabilitation Center.Exercises are provided by the trained sports instructor.Each person receives a bone scan (DXA) and a blood sample at the beginning and end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age over 65 years old;Fat percentage greater than 32% or BMI greater than 30%;T-score < -1.0; The power of the Handgrip Strength is less than 21kg in the age range of 65 to 80 years Exit criteria:Chronic diseases such as high blood pressure; thyroid disease; severe kidney disease, cancer, diabetes or ,osteoporosis (T-score < -2.5); Parallel Physical Exercises ;Following a weight loss diet of more than 5kg in the last three months; Hormone therapy or taking any medication that affects bone density, fat tissue, or hormonal system.

Intervention groups
Participants in the intervention group participate in a special training program. Participants are requested to conduct a sports protocol during the course of the study. Participants in both groups are asked to continue their previous food program.

Main outcome variables
Serum levels of sclerostin; Serum levels of troponin T

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180627040260N1**
Registration date: **2018-11-27, 1397/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-27, 1397/09/06**
Update count: **0**

Registration date
2018-11-27, 1397/09/06

Registrant information

Name
Mohammadali Dayani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 38 3224 4194

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2018-12-22, 1397/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Study of Effect of a 24-Weeks Period of Elastic Resistance Band Training on Biomarkers of Osteosarcopenia Obesity in Osteosarcopenic Obese Women

Public title
Effect of Elastic Resistance Band Training on Biomarkers of Osteosarcopenia obesity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 65 years old, Fat percentage greater than 32% or BMI greater than 30%, T-score < -1.0, The power of the Handgrip Strength is less than 21kg, Age range of 65 to 80 years

Exclusion criteria:
Chronic diseases such as high blood pressure, thyroid disease, severe kidney disease, cancer, diabetes or ,osteoporosis (T-score < -2.5) Parallel Physical Exercises Following a weight loss diet of more than 5kg in the last three months Hormone therapy or taking any medication that affects bone density, fat tissue, or hormonal system.

Age
From **65 years** old to **80 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After completing the initial evaluations, subjects are randomly assigned to the training or control group in a 1: 1 ratio using block randomization based on age (60 to 80 years) (stratified blocked randomization) using Unspecified seal envelopes are assigned. A research assistant, not directly involved in the evaluation, generates block size and random sequences using a computer that is hidden from the study researcher.

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 of Medical Sciences

Street address
Educational Complex of Shahrekord University of Medical Sciences, Rahmatieh,Shahrekord

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
88155571

Approval date
2018-04-22, 1397/02/02

Ethics committee reference number
IR.SKUMS.REC.1397.019

Health conditions studied

1

Description of health condition studied
Oosteo sarcopenic obesity syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
troponin t

Timepoint
24 hours before the intervention and 48 hours after the end of the workout

Method of measurement
ELISA KIT,96 WELLS

2

Description
Sclerostin

Timepoint
24 hours before the intervention and 48 hours after the end of the workout

Method of measurement
ELISA KIT,96 WELLS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Individuals in the intervention group participate in a special training program. Participants in

both groups are asked to continue their previous diet. The personalized training program using rubber bands (Thera-Band®, The Hygenic Corporation, Akron, OH, USA) is a two training sessions per week course for the duration of 24 weeks which leads to a total of 48 sessions. The program will include 10 minute warm-up and cool down stretching exercises at the beginning and end of each training session. Each session will be a 60 minute resistance training using rubber bands (the extent and intensity of exercise will be increased over the time). Intend resistance exercises will be the alternative training of upper and lower body large muscles. Using rubber bands will cause the needed resistance overload. This type of resistance loading is chosen for both ease of use and performance, also it is suitable for elderly people who did not previously engage in physical activities. Intensity of loading was adjusted using color coded rubber bands (based on strengths yellow, red, green and blue). Intensity of initial resistance load for each individual was chosen based on their ability to do 15-20 repetitions. Each two weeks the training program is reviewed and if the individuals can do 30 repetitions the strength of rubber band will be increased. Each resistance session of training with rubber bands would also include exercising one or two groups of major muscles (legs, back, stomach, chest, shoulders, and arms). These exercises include: seated rowing exercise, standing body rotation, squat, leg press, crunching, preacher curls with two hands, lateral flexion, triceps extension, bench press, and dorsiflexion of ankles. Completion of all ten mentioned exercises is counted as one cycle. To induce standard resistance, rubber band should be stretched to 100% of rest lengths. Training speed of each internal and external phase of sessions should be 4seconds. Each session consists of 3 cycles.

Category

Treatment - Other

2

Description

Control group: The control group only performs daily activities.Participants are asked to continue their past food program

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Mohammadali Dayani

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Parastar Street,Shariati Blvd,Shahrekord,Chaharmahal & Bakhtiari Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Sayyed Kamal Solati

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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

Shahre-kord 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

The University of Shahrekord

Full name of responsible person

Ebrahim Banitalebi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In the form ofThesis
When the data will become available and for how long
1397
To whom data/document is available
For all audiences
Under which criteria data/document could be used
For all audiences
From where data/document is obtainable
Shahrekord Medical University
What processes are involved for a request to access data/document
In the form ofThesis
Comments