

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Sep 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)

Phone

+98 38 3224 4194

Email address

dayani@skums.ac.ir

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

Osteo 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

Street address

Parastar Street,Shariati

Blvd,Shahrekord,Chaharmahal & Bakhtiari Province

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Sayyed Kamal Solati

Street address

Headquarters of the University,Kashani

BLVD,shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Phone

+98 38 3334 2414

Email

vcrt@skums.ac.ir

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

Street address

Rahbar Blvd, Shahrekord University,

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۳۴۱۴۱۸۸۱۸۶

Phone

+98 383232440

Email

banitalebi.e@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammadali Dayani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Radiology

Street address

Parastar Street, Shariati

Blvd, Shahrekord, Chaharmahal & Bakhtiari Province

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۶۷۵۸۹۱۵

Phone

+98 38 3224 4194

Fax**Email**

dayani@skums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammadali Dayani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Radiology

Street address

Ayatollah kashani hospital, parastar street, shehrekord town

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۶۷۵۸۹۱۵

Phone

+98 38 3224 4194

Fax**Email**

dayani@skums.ac.ir

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 of Thesis

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 of Thesis

Comments