

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of 8 weeks of combined exercises with and without blood flow restriction and vitamin D intake on serum levels of alkaline phosphatase and C reactive exercise (crp) and muscle quality of elderly women.

Protocol summary

Study aim

Determining the effect of 8 weeks of combined exercises with and without blood flow restriction and vitamin D supplementation on the serum levels of alkaline phosphatase and C-reactive protein (CRP) and muscle quality of elderly women.

Design

Clinical trial with control group, with parallel groups, randomized, on 40 elderly people. Randomization by the method of equal blocks (10 blocks of 4) in which a number of intervention people and a number of comparison people are included in each block.

Settings and conduct

By referring to the rehabilitation and physiotherapy clinic, eligible people were identified and placed in the intervention groups using equal blocks (10 blocks of 4) randomization. Then, people will go to the sports club for training intervention and perform exercises and supplements for 8 weeks. And before and 24 hours after exercise interventions, blood samples are taken from people to be measured in the laboratory.

Participants/Inclusion and exclusion criteria

Entry requirements: Age range between 65 and 75 years
Conditions of non-entry: inability to do exercises

Intervention groups

Group of combined exercises and supplements: in the group of combined exercises, the samples perform exercises with blood flow restriction (BFR) and without blood flow restriction, and the supplement group takes vitamin D supplements, and the control group does not undergo any intervention.

Main outcome variables

serum levels of alkaline phosphatase and reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056548N5**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

Registration date

2023-03-01, 1401/12/10

Registrant information

Name

Saeid Shamlou kazemi

Name of organization / entity

Bu-Ali Sina university

Country

Iran (Islamic Republic of)

Phone

+98 912 859 7297

Email address

saeidshamlou9092@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-28, 1401/12/09

Expected recruitment end date

2023-03-29, 1402/01/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks of combined exercises with and without blood flow restriction and vitamin D intake on serum levels of alkaline phosphatase and C reactive exercise (crp) and muscle quality of elderly women.

Public title

Effect of exercise, vitamin D supplementation on serum levels of alkaline phosphatase and reactive protein(crp)

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

elderly

Exclusion criteria:

History of cardiovascular disease

Age

From **65 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

By referring to the rehabilitation and physiotherapy clinic, eligible people were identified and placed in the intervention groups using equal blocks (10 blocks of 4) randomization. In this randomization, the method of equal blocks (10 blocks of 4) was used, in which a number of intervention people and a number of comparison people are included in each block, and we assigned them to different groups. The method and tool of block random sequence generation has been done using <https://www.sealedenvelope.com/simple-randomiser/v1/lits>.

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 Sports Science Research Institute

Street address

Fifth Alley, Mir Emad Ave., Ostad Motahari Ave

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Tehran

Province

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Postal code

1474674646

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.SSRI.REC.1401.1583

Health conditions studied

1

Description of health condition studied

Elderly

ICD-10 code

O09.52

ICD-10 code description

elderly

Primary outcomes

1

Description

The percentage of elderly people in the community with improvement of alkaline phosphatase level

Timepoint

Measurement of alkaline phosphatase levels before and after the intervention

Method of measurement

ALP bone isozyme test

2

Description

The percentage of elderly people in the community with decreased levels of reactive protein

Timepoint

Measurement of reactive protein levels before and after the intervention

Method of measurement

By testing blood samples

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: combined exercises (aerobic-resistance) of an 8-week program will include three training sessions per week and about one hour per day.

Before starting the exercise, the subjects warm up for 10 minutes with stretching and stretching movements, and at the end of the exercise, they cool down with stretching movements for 10 minutes. Resistance exercises include two lower body movements (leg press, knee extension) and two upper body movements (front arm, back arm). Leg, front thigh, front arm and back arm press movements with intensity (80% of one maximum repetition) three sets with 8-12 repetitions for the first group and intensity of 20-30% of one maximum repetition (three sets until exhaustion) for groups The second and third work is done with weights. In the subjects of the third group, blood flow restriction is done by closing the elastic bands in the proximal part of both legs during lower body exercises or both arms during upper body exercises. In the supplement group, vitamin D supplement in the form of 50,000 mg capsules will be used once every two weeks.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Vahedi Physical Medicine and Rehabilitation Center

Full name of responsible person

Saeid shamlou kazemi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Danesh Alborz University

Full name of responsible person

Saeid Shamlou Kazemi

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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

Danesh Alborz University

Proportion provided by this source

10

Public or private sector

Private

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**

Bu-Ali Sina University

Full name of responsible person

Saeid Shamlou Kazemi

Position

Student

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If the intellectual rights are preserved, the data can be sent to the researchers.

From where data/document is obtainable

Email address: saeidshamlou9092@gmail.com

What processes are involved for a request to access data/document

Submission of a written request (one week)

Comments