Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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/lists.
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
City
Tehran
Province
Tehran
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

Street address

Jahan Shahr Ave, Ostandari Ave

City

کرج

Province

Tehran

Postal code

3149915968

Phone

+98 26 3444 9975

Email

saeidshamlou9092@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Danesh Alborz University

Full name of responsible person

Saeid Shamlou Kazemi

Street address

MAhdiywh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3221 0929

Email

saeidshamlou9092@gmail.com

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

Street address

Mahdiyeh AVE

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3221 0929

Email

saeidshamlou9092@gmail.com

Person responsible for scientific 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

Street address
Mahdiyeh street
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3221 0929
Fax
Email
saeidshamlou9092@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Bu-Ali Sina University
Full name of responsible person
Saeid Shamlou Kazemi
Position
Student
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Sport Medicine
Street address
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Province
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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