Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 2026

The effect of a course of resistance training with calcium plus vitamin D supplementation on the level of growth factor beta 1(TGF-β1) and high-sensitive C reactive protein (hs-CRP)

Protocol summary

Study aim

The aim of the present study was to investigate the protective effect of training combined with calcium and vitamin D supplementation on inflammatory factors in elderly men.

Design

A controlled clinical trial with parallel groups (supplement and training, placebo and training and control), double-blind, on 45 elderly people. A random number table was used for randomization.

Settings and conduct

After selecting 45 eligible elderly men who were referred to health centers in Zabol city and grouping the individuals, for four weeks, the exercise groups will follow three exercise sessions with an intensity of 65 to 75% of one repetition maximum per week, and the supplement groups will follow a program of one 1000 mg calcium tablet per day along with one 50,000 international unit vitamin D capsule per week. For double-blinding, before the start of the study, the packages containing the supplement and placebo will be marked by a person other than the researcher, and the supplement and placebo will be consumed under the supervision of the same person.

Participants/Inclusion and exclusion criteria

Age range: 60-70 years, BMI between 18.5 and 25 kg/m2, having a general level of physical and mental health, inactive lifestyle. Exclusion criteria: using walking aids, using medication in the previous 6 months, having cardiovascular diseases

Intervention groups

Intervention group 1: Training with supplement, one 1000 mg calcium tablet per day along with one 50,000 IU vitamin D capsule per week and resistance squat exercises 3 sessions per week. Intervention group 2: Training with placebo, one 1000 mg placebo tablet per day along with one 50,000 IU placebo capsule per week and resistance squat exercises 3 sessions per week. Control group: Following daily activities without supplement and exercise

Main outcome variables

growth factor beta 1 and high-sensitive C reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220322054338N2**
Registration date: **2025-01-03, 1403/10/14**
Registration timing: **prospective**

Last update: **2025-01-03, 1403/10/14**
Update count: **0**

Registration date

2025-01-03, 1403/10/14

Registrant information

Name
elham ghasemi
Name of organization / entity
University of Sistan and Baluchestan
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date
2025-02-18, 1403/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of a course of resistance training with calcium plus vitamin D supplementation on the level of growth factor beta 1(TGF-β1) and high-sensitive C reactive protein (hs-CRP)

Public title
The effect of resistance training with calcium plus vitamin D supplementation on the level of growth factor beta 1(TGF-β1) and high-sensitive C reactive protein (hs-CRP)
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age range is 60-70 years BMI between 18.5- 25 kg/m2 Inactive lifestyle (exercise activity less than 1 hour per week) Having general physical and mental health
Exclusion criteria:
Using aids for walking Using the drug in the previous 6 months Having chronic diseases, especially cardiovascular diseases
Age
From **60 years** old to **70 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Number randomization was performed using Random Allocation software using permutation block method. The numbers are sorted into three blocks and assigned to the codes A, B and C. That the codes A, B, and C are unknown for the researcher.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in the supplement groups will consume 1000 mg of calcium per day along with 50,000 IU of vitamin D per week, while those in the placebo groups will be prescribed starch tablets and capsules in the same number and frequency as the supplement group. Before the study begins, the containers containing the supplement and placebo will be marked by a person other than the researcher to ensure that neither the researcher nor the participants know which capsules they are receiving. Supplement and placebo intake was done under the supervision of the same person.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Committee of Ethics in Research of University of Sistan and Baluchistan
Street address
University blvd
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816745845
Approval date
2024-11-09, 1403/08/19
Ethics committee reference number
IR.USB.REC.1403.044

Health conditions studied

1

Description of health condition studied
Aging
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
growth factor beta 1
Timepoint
Beginning and end of the study after 4 weeks
Method of measurement
ELISA

2

Description
high-sensitive C reactive protein
Timepoint
Beginning and end of the study after 4 weeks
Method of measurement
ELISA

Secondary outcomes

1

Description
Weight
Timepoint
Beginning and end of the study after 4 weeks
Method of measurement
digital scale

Intervention groups

1

Description
Intervention group: training with supplement, one 1000 mg calcium tablet per day along with one 50,000 IU vitamin D capsule per week and resistance squat exercises 3 sessions per week for 4 weeks
Category
Treatment - Other

2

Description
Intervention group: training with placebo, one 1000 mg placebo tablet per day along with one 50,000 IU placebo capsule per week and resistance squat exercises 3 sessions per week for 4 weeks
Category
Treatment - Other

3

Description
Control group: following daily activities without supplement and exercise for 4 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Zabol city
Full name of responsible person
Elham Ghasemi
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Sponsors / Funding sources

1

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Name of organization / entity
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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
University of Sistan and Baluchestan
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
University of Zabol
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Elham Ghasemi
Position
Assistant Professor of department of Sport Sciences
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Participants' information will be made available to other researchers after being de-identified

When the data will become available and for how long

After the publication of the final research report.

To whom data/document is available

Researchers

Under which criteria data/document could be used

Citing the findings by citing the source

From where data/document is obtainable

Those interested in more information can contact the following email and address: Postal address: University of Zabol Email: elhamghasemi@uoz.ac.ir

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

Those interested in more information can contact the following email and address: Postal address: University of Zabol Email: elhamghasemi@uoz.ac.ir

Comments