Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

The effect of a course of vitamin D and calcium supplementation along with squat exercises on angiogenesis indices in the elderly

Protocol summary

Study aim

The aim of the present study was to investigate the protective effect of exercise combined with calcium and vitamin D supplementation on angiogenesis indices in elderly men.

Design

The clinical trial will be a controlled, double-blind, parallel-group trial (supplement and exercise, placebo and exercise and control) on 45 elderly people. A random number table will be 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 5% of body weight 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 taken 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 squat exercises 3 sessions per week. Intervention group 2: Training with placebo, one 1000 mg placebo tablet per day along with one placebo capsule per week and squat exercises. Control group: Continuing daily activities without intervention

Main outcome variables

Vascular endothelial growth factor, Nitric oxide, Fibroblast growth factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220322054338N3**
Registration date: **2025-03-29, 1404/01/09**
Registration timing: **prospective**

Last update: **2025-03-29, 1404/01/09**
Update count: **0**

Registration date

2025-03-29, 1404/01/09

Registrant information

Name

elham ghasemi

Name of organization / entity

University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

Phone

+98 54 3123 2080

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-04, 1404/01/15

Expected recruitment end date

2025-05-05, 1404/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a course of vitamin D and calcium supplementation along with squat exercises on angiogenesis indices in the elderly

Public title

The effect of vitamin D and calcium supplementation and squat exercises on angiogenesis indices in the elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range is 60-70 years BMI between 18.5- 25 kg/m2 Inactive lifestyle Having general physical and mental health

Exclusion criteria:

Inability to walk Using the drug 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

Randomization of numbers is done using Random Allocation software and permutation block method. People will be assigned to three groups using ternary permutation blocks. To do this, the letters A, B, and C will be considered for the two intervention and control groups, respectively. The possible states in the ternary block are six states including CAB, BCA, CBA, ACB, BAC, ABC. Each state will be written on a card. The cards will be assigned numbers one to six. Then, one of the six possible states will be selected using dice and based on that, the selected patients will be assigned to three groups. This process will continue until the sample size is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the supplement group will receive 1,000 mg of calcium daily and 50,000 IU of vitamin D weekly. The placebo groups will receive the same number of starch tablets and capsules. Before the study begins, the supplement and placebo packages will be marked by someone other than the researcher so that the researcher and participants are unaware of the type of capsules they are receiving. The supplement and placebo will be administered 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

Elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fibroblast growth factor

Timepoint

Beginning and end of the intervention

Method of measurement

ELISA

2

Description

Nitric Oxide

Timepoint

Beginning and end of the intervention

Method of measurement

ELISA

3

Description
Vascular endothelial growth factor
Timepoint
Beginning and end of the intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
Body Mass Index
Timepoint
Beginning and end of the intervention
Method of measurement
Inbody70 body composition analyzer

Intervention groups

1

Description
Intervention group: 4 weeks of training with supplements, one 1000 mg calcium tablet per day along with one 50000 international units of vitamin D capsule per week and squat exercises 3 sessions a week.
Category
Treatment - Other

2

Description
Intervention group: 4 weeks of placebo training, one 1000 mg placebo tablet (containing lactose and edible paraffin) per day, along with one 50,000 IU placebo capsule (corn starch and Avicel) per week, and resistance squat training 3 sessions per week.
Category
Placebo

3

Description
Control group: Tracking activities and daily regimen without any interference
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

Sponsor
Name of organization / entity
Vice President for Research, University of Sistan and Baluchestan
Full name of responsible person
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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
Vice President for Research, 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
Full name of responsible person
Elham Ghasemi
Position
Assistant Professor of department of Sport Sciences

Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 through the email and address below: Mailing 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 through the email and address below: Mailing address: University of Zabol Email: elhamghasemi@uoz.ac.ir
Comments