

# 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

Vascular endothelial growth factor, Nitric oxide, Fibroblast growth factor

#### 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/m<sup>2</sup>, 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

#### 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

##### Email address

elhamghasemi@uoz.ac.ir

##### 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

##### **Street address**

Kilometer two of Bonjar road

#### **City**

zabol

#### **Province**

Sistan-va-Balouchestan

#### **Postal code**

98613-35856

#### **Phone**

+98 54 3123 2082

#### **Email**

elhamghasemi@uoz.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice President for Research, University of Sistan and Baluchestan

##### **Full name of responsible person**

Dr. Nour mohammad Yaqhoubi

##### **Street address**

Daneshgah blvd.

##### **City**

Zahedan

##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Email**

yagoubi@mgmt.usb.ac.ir

#### **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**

Ph.D.

**Other areas of specialty/work**

Physiology

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**Other areas of specialty/work**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

University of Sistan and Baluchestan

**Full name of responsible person**

Dr. Shila Nayebifar

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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shila\_nayebifar@ped.usb.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

University of Zabol

**Full name of responsible person**

Elham Ghasemi

**Position**

Assistant Professor

**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**