Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The effect of eight weeks of selenium supplementation and Concurrent training on SOD, CAT, CRP, GPX, GR and lipid profile in elderly men

Protocol summary

Study aim

The purpose of this study is to investigate the effect of eight weeks of selenium supplementation with concurrent training on SOD CAT, CRP, GPX and lipid profiles of elderly men.

Design

A clinical trial with a pre-test-post-test semi-experimental design with a control group, double-blind, phase 4 on 48 elderly men using the PASS 2023 software (NCSS, LLC, Kaysville, Utah, USA, ncss.com/software/pass) the subjects will be divided into 6 parallel groups of 8 people and will be placed in one of the following groups: supplement, placebo, control, concurent training, concurent training+supplement, concurent training+placebo. The supplement groups will receive 200 micrograms of Selenium supplement with the American brand Naturemid. Maltodextrin will also be used as a placebo and in completely similar capsules as a placebo. The training program will be done 3 days a week on non-consecutive days for 8 weeks, each session will be 60 minutes in the morning.

Settings and conduct

This study will be conducted in Kahrizak home of Alborz province on the elderly in a double blind method (subjects, researchers and executive staff and data analyzers are not aware of the contents of the capsules until the end of extracting the results).

Participants/Inclusion and exclusion criteria

The criteria for inclusion in the study are elderly men with the age of at least 65 and at most 75 years, the ability to perform physical and daily activities, the absence of underlying diseases such as diabetes, cardiovascular disease, and skeletal and joint abnormalities.

Intervention groups

After selecting the subjects, 48 elderly men will be divided into 6 groups of 8 people: supplement, placebo, control, concurent training, concurent training group+supplement, concurent training+placebo.

Main outcome variables

Improving the condition of the elderly using a combination of supplements and exercise

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180912041018N3**
Registration date: **2023-11-20, 1402/08/29**
Registration timing: **prospective**

Last update: **2023-11-20, 1402/08/29**
Update count: **0**

Registration date

2023-11-20, 1402/08/29

Registrant information

Name

Rouhollah Haghshenas

Name of organization / entity

Semnan

Country

Iran (Islamic Republic of)

Phone

+98 23 3336 3494

Email address

rhm@semnan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-01-25, 1402/11/05

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of eight weeks of selenium supplementation and Concurrent training on SOD, CAT, CRP, GPX, GR and lipid profile in elderly men

Public title
Investigation of the effect of selenium and exercise on the elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The age range of the subjects should be between 65 and 75. Subjects must be able to perform daily activities and physical activity.
Exclusion criteria:
Use of antioxidant supplements up to 6 months before conducting the research Having chronic diseases, such as cardiovascular diseases, diabetes, acute joint disease, osteoporosis, bone fractures
Age
From **65 years** old to **75 years** old
Gender
Male

Phase
4
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
After finalizing the 48 subjects and assigning codes 1 to 48 to each subject individually and using the PASS 2023 software (NCSS, LLC, Kaysville, Utah, USA, ncss.com/software/pass), the subjects were will be randomly divided into 6 groups of 8 people.
Blinding (investigator's opinion)
Double blinded
Blinding description
This research will be done in a double blind way. After explaining the conditions and how to conduct the research to the subjects, they will be divided into six groups. Supplemental group, placebo group, control group, concurrent training group, concurrent training+supplement group, concurrent training+placebo group. None of the participants, the executive staff of nurses, physiotherapists, etc., practitioners and students (researcher) will know about the contents of the capsules. Which group will use the supplement and which group will use the placebo, the subjects and the researcher will not know. And this work will be determined by a third party as a reference person. In this way, the capsules containing placebo and supplement will be coded and provided by the researcher to the specified groups. At the end of the research and after collecting the blood sample and measuring the dependent variables, the data will be collected and provided to the supervisor, and after the data analysis and the results are determined, the codes will be opened and the supplement and placebo groups will be determined.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Semnan University of Medical Sciences and Health Services
Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran.
City
Semnan
Province
Semnan
Postal code
35147-99442
Approval date
2023-07-31, 1402/05/09
Ethics committee reference number
IR.SEMUMS.REC.1402.100

Health conditions studied

1

Description of health condition studied
Aging
ICD-10 code
Z10
ICD-10 code description
Factors influencing health status and contact with health services, Routine general health check-up of defined subpopulation,

Primary outcomes

1

Description

Glutathione peroxidase

Timepoint

Measurement of glutathione peroxidase at the beginning of the study (before the start of the intervention) and 48 hours after the last training session.

Method of measurement

By ELISA method and using ELISA kit

2

Description

Glutathione reductase

Timepoint

Measurement of Glutathione reductase at the beginning of the study (before the start of the intervention) and 48 hours after the last training session.

Method of measurement

by ELISA method and using ELISA kit

3

Description

C Reactive Protein

Timepoint

Measurement of C-reactive protein at the beginning of the study (before the start of the intervention) and 48 hours after the last training session and in the fasting state.

Method of measurement

By ELISA method and using ELISA kit

4

Description

Superoxide Dismutase

Timepoint

At the beginning of the study (before the start of the intervention) and 48 hours after the last training session and in the fasting state.

Method of measurement

By ELISA method and using ELISA kit

5

Description

Catalase

Timepoint

At the beginning of the study (before the start of the intervention) and 48 hours after the last training session and in the fasting state.

Method of measurement

By ELISA method and using ELISA kit

Secondary outcomes

1

Description

low-density lipoproteins

Timepoint

At the beginning of the study (before the start of the intervention) and 48 hours after the last training session and fasting state

Method of measurement

ELISA method and use of ELISA kit

2

Description

very low density lipoprotein

Timepoint

At the beginning of the study (before the start of the intervention) and 48 hours after the last training session and fasting state

Method of measurement

ELISA method and use of ELISA kit

3

Description

Cholesterol

Timepoint

At the beginning of the study (before the start of the intervention) and 48 hours after the last training session and fasting state

Method of measurement

ELISA method and use of ELISA kit

4

Description

Triglyceride

Timepoint

At the beginning of the study (before the start of the intervention) and 48 hours after the last training session and fasting state

Method of measurement

ELISA method and use of ELISA kit

Intervention groups

1

Description

Intervention group 1: Concurrent training, 3 sessions per week, 60 minutes in the morning, strength and endurance training protocol will be performed on every other day and on even days.

Category

Rehabilitation

2

Description

Intervention group 2: Supplement who will consume 200 micrograms of Selenium supplement with Nature med brand made in the USA.

Category

Other

3

Description

Intervention group 3: Concurrent training and supplementation, in addition to implementing the weekly Concurrent training protocol, three sessions of 60

minutes per session will consume 200 micrograms of selenium supplement daily.

Category

Rehabilitation

4

Description

Intervention group 4: Placebo, who will consume a capsule containing roasted wheat flour and similar to the capsule containing selenium.

Category

Placebo

5

Description

Intervention group 5: Exercise and placebo, in addition to implementing the Concurrent training protocol three sessions a week, each session will take 60 minutes a day, a capsule containing a placebo (roasted wheat flour) and completely similar to the selenium capsule.

Category

Placebo

6

Description

Control group: The control will have the same conditions as the other groups and will not receive any of the interventions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran, Karaj, Kehrizak Nursing Home, Alborz Province

Full name of responsible person

Ali Nowrozi

Street address

at the beginning of Esfahani Street, at the end of Golstanak St, Mohammadshahr

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Karaj

Province

Alborz

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Fax

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Email

Kahraj@kahrizak.com

Web page address

https://kahrizakcharity.com/kahrizak-alborz-intro

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University

Full name of responsible person

Rouhollah Haghshenas

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5 km of Damghan road

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rhm@semnan.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University

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

Semnan University

Full name of responsible person

Rouhollah Haghshenas

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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5 km of Damghan road

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University

Full name of responsible person

Rouhollah Haghshenas

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the main outcomes will be published as articles in journals.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For use in review articles and meta-analysis

From where data/document is obtainable

Rouhollah Haghshenas, Email: rhm@semnan.ac.ir

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

One week after the applicant's request and necessary checks, the necessary information will be sent via email.

Comments