

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Study the Effect of Concurrent Training and Supplementation of L-Arginine on SIRT6, FBS and Body Composition in Elderly men

Protocol summary

Study aim

Investigating the effect of concurrent training and L-Arginine supplementation on SIRT6, FBS and body composition in elderly men

Design

44 elderly non-athlete men will be divided into four groups [Exercise +Supplement (ES) group; Exercise +Placebo (EP) group; Supplement (S) group and Control (C) group], in the form of randomized, controlled clinical trial with a parallel group design and blinded outcome assessment.

Settings and conduct

The exercise protocol of this study will be conducted in a sports club, under the supervision of a physician, researcher and trainer in this field. In this study, blinding will be done in the information gathering stage by a person who is completely unaware of the presence of individuals in the groups.

Participants/Inclusion and exclusion criteria

44 elderly non-athlete men will be selected. The inclusion criteria are as follows: male gender, $60 \leq \text{age} \leq 75$ years, no systematic strength training last 6 months, Written willingness and informed consent to participate in the study. Exclusion criteria were: Orthopedic, cardiovascular and respiratory problems, disability to do strength training, consumed of antioxodant supplement.

Intervention groups

subjects will be randomly divided into four equal-sized groups; Exercise +Supplement (ES) group; Exercise +Placebo (EP) group; Supplement (S) group and Control (C) group.

Main outcome variables

Rate of sirt6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180912041018N2**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

Registration date

2019-02-10, 1397/11/21

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

2018-02-20, 1396/12/01

Expected recruitment end date

2019-04-17, 1398/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the Effect of Concurrent Training and Supplementation of L-Arginine on SIRT6, FBS and Body Composition in Elderly men

Public title

Study the Effect of Exercise Training and
Supplementation of L-Arginine in elderly men

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

males in range of $60 \leq \text{age} \leq 75$ years Being able to do
exercise movements

Exclusion criteria:

Having systematic strength training last 6 months (At
least more than one session per week) having to
cardiovascular disease and joint and bone problems
Bone fractures Use of any kind of antioxidant
supplements

Age

From **60 years** old to **75 years** old

Gender

Male

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Using NCSS PASS11 software, Procedure menu, DOE
submenu, subjects were randomly will be divided into
four equal-sized groups

Blinding (investigator's opinion)

Single blinded

Blinding description

Since Exercise training cannot be masked in a way as,
for instance, pharmacological substances, so an
important level of blinding in exercise science research
remains with the data collectors. In this single-blind
study, due to the nature of the method, blinding will be
done in the information gathering stage by a person who
is completely unaware of the presence of individuals in
the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Tabriz University of Medical

Sciences

Street address

Niayesh

City

tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-03-05, 1396/12/14

Ethics committee reference number

IR.TBZMED.REC.1396.1136

Health conditions studied

1

Description of health condition studied

aging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sirtuin-6

Timepoint

Measuring Sirtuin-6 in the start of the study and 48 hours
after the last training session

Method of measurement

Sirtuin6 concentrations assaye in plasma according to
the manufacturers' instructions using ELISA kits specific
for human

2

Description

Glucose

Timepoint

Measuring Glucose in the start of the study and 48 hours
after the last training session

Method of measurement

برای اندازه گیری گلوکز خون از روش آنزیماتیک کالری متری و کیت
شرکت پارس آزمون ایران و به ترتیب با دقت و حساسیت 1.3 % و 1
mg/dl استفاده خواهد شد

3

Description

Body Composition

Timepoint

Measuring Body Composition in the start of the study
and 48 hours after the last training session

Method of measurement

Body Composition will be calculated as weight (kg)
divided by the square of the height (m2)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First group of concurrent training+ supplement of L-arginine that in addition to the concurrent training, performed three sessions per week (coupled days), daily each subject received 1,000 mg of L-Arg capsule contain of L-arginine Hydrochloride, Microcrystalline Cellulose, P.V.P, Magnesium, Stearate after breakfast with full stomach.

Category

Rehabilitation

2

Description

Intervention group: second, group of concurrent training+placebo, which in addition to implementing the exercise protocol three sessions per week for eight weeks, will also use placebo capsules similar to capsules of supplementary groups filled with maltodextrin. It should be noted that the investigator and subjects will not be informed of the contents of the capsule until the end of the protocol.

Category

Placebo

3

Description

Intervention group: Third, group of supplement that for eight weeks, daily received 1,000 mg of placebo capsules .The capsules will have identical shape and appearance and contained L-Arg Hydrochloride, Microcrystalline Cellulose, P.V.P, Magnesium, Stearate (Karen Pharma & Food Supplement Co) Prepared from Karen Pharmaceutical Company PNC, code 6261405113328 approved by the Ministry of Health of Iran.

Category

Other

4

Description

Control group: There was no intervention on them, only they were asked to continue their normal life

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahreza Nursing Home

Full name of responsible person

Neda Gilani

Street address

Pasdaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

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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

Tabriz University of Medical Sciences

Proportion provided by this source

60

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

Tabriz University of Medical Sciences

Full name of responsible person

Neda Gilani

Position

Assistant Professor of Biostatistics

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

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Semnan University

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)**

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The SPSS data used to support the findings of this study are available from the corresponding author upon request.

When the data will become available and for how long

The SPSS data used to support the findings of this study are available from the corresponding author upon request.

To whom data/document is available

The SPSS data used to support the findings of this study are available from the corresponding author upon request.

Under which criteria data/document could be used

By authorizing the corresponding author and maintaining all the material and spiritual rights

From where data/document is obtainable

The SPSS data used to support the findings of this study are available from the corresponding author upon request.

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

The SPSS data used to support the findings of this study are available from the corresponding author upon request.

Comments