

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Improvement of muscle strength and circulatory levels of plasma Follistatin and Myostatin following resistance training and Epicatechin supplementation in sarcopenic older adults

Protocol summary

Summary

The purpose of this study is to investigate the effect of eight weeks resistance training, Epicatechin supplementation and the combined effect of these two interventions on plasma levels of Myostatin and Follistatin in sarcopenic older adults. The present study is semi-experimental and developmental with pre-test and post-test design. Inclusion criteria consist of sarcopenic, non-athletic elderly males aged 65-75 years and exclusion criteria consist of the history of special diseases and the use of any type of drug or supplement. A week prior to the initial tests, all participants will attend an orientation session in which they will be informed about the objectives and methods of conducting the research by exercise science specialists. Initial tests will be performed in the morning a week before the study to select qualified people and homogenize groups. Their height, weight, body mass index, AMMI, mobility, the degree of involvement in physical activities, health condition, and isotonic maximal strength will be measured and 56 subjects randomly will assign to 4 groups (using the table of random numbers method): resistance training+placebo (n=13), resistance training+epicatechin (n=14), epicatechin (n=15) and placebo (n=14). Forty-eight hours before the 8-week intervention, fasting blood samples will be taken from participants' arm vein to evaluate the study variables. Then, subjects of the training groups will perform the training protocol 3 days a week at 5 p.m. for eight weeks. During the same time, individuals in the supplement groups will take epicatechin supplements at 4 p.m. every day (1mg/kg/day). In order to control the psychological effects of taking the supplement, members of the placebo group will receive placebo capsules (starch) which are similar to the epicatechin capsules in terms of shape and color. The subjects of the placebo group will

not participate in any exercise training during the intervention time. Fasting blood samples will be obtained from all the participants two days following the last training session (hence, posttest).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101423002N4**

Registration date: **2017-10-31, 1396/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-31, 1396/08/09

Registrant information

Name

Alireza Ghardashi Afousi

Name of organization / entity

University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 8201 5031

Email address

ghardashi.a@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2017-04-08, 1396/01/19

Expected recruitment end date

2017-06-01, 1396/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Improvement of muscle strength and circulatory levels of plasma Follistatin and Myostatin following resistance training and Epicatechin supplementation in sarcopenic older adults

Public title

Effect of resistance training and Epicatechin on Sarcopenia

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: males between the age of 65-75 years; suffering from class I sarcopenia (AMMI: less than 10.75 kg.m⁻²); and having no training experiences over the past 12 months before the study. Exclusion criteria: having a history of specific diseases (e.g. valvular heart disease (VHD), ischemic heart disease (IHD); chronic lung disease (COLD); hypertrophic cardiomyopathy (HCM); hyperlipoproteinemia (HLP); hypertension (HTN)); unwillingness to participate in the study; smoking; using supplements or drugs over the past month before the study; suffering from psychological diseases (e.g. mental disorder); and suffering from muscle and joint injuries (e.g. slip disk in the back).

Age

From **65 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University of Tehran

Street address

16th Azar Street, Enghelab Square, Central Organization of University of Tehran

City

Tehran

Postal code**Approval date**

2017-02-16, 1395/11/28

Ethics committee reference number

IR.UT.Rec.1395010

Health conditions studied**1****Description of health condition studied**

Sarcopenia

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Follistatin

Timepoint

Before starting the intervention, after eight weeks intervention

Method of measurement

Blood sample, ELISA method with special kit

2**Description**

Myostatin

Timepoint

Before starting the intervention, after eight weeks intervention

Method of measurement

Blood sample, ELISA method with special kit

Secondary outcomes**1****Description**

BMI

Timepoint

Before and after the intervention

Method of measurement

weight(kg) / height to the power of 2 (cm)

2

Description

AMMI

Timepoint

Before and after the intervention

Method of measurement

DXA

3

Description

up and go test

Timepoint

Before and after the intervention

Method of measurement

measuring the test time

4

Description

physical activities rate

Timepoint

Before and after the intervention

Method of measurement

Via The Physical Activity Scale for the Elderly questionnaire /PASE

5

Description

physical health condition

Timepoint

Before and after the intervention

Method of measurement

using PAR-Q questionnaire

6

Description

Maximal Strength

Timepoint

Before and after the intervention

Method of measurement

1RM test

Intervention groups

1

Description

Exercise+Placebo group: participants of this group performed 8 weeks resistance training (at 5 to 6 p.m., three sessions per week, each session took approximately 60 minutes, with 60-80% of one repetition maximum). In addition, during this 8-week period this group received one capsule similar to Epicatechin capsules (in terms of color and shape) with 200 ml water daily, at the same time as the supplement group (one hour before doing resistance training, at 4 p.m.).

Category

Placebo

2

Description

Placebo group: participants of this group will receive one capsule similar to Epicatechin capsules (in terms of smell and shape) daily with 200 ml water for 8 weeks, at the same time as the supplement group (at 4 p.m.).

Category

Placebo

3

Description

Exercise+supplement group: participants of this group performed 8 weeks resistance training (at 5 to 6 p.m., three sessions per week, each session took approximately 60 minutes, with 60-80% of one repetition maximum). In addition, during this 8-week period this group consumed one Epicatechin capsule daily (1 mg/kg/day), with 200 ml water, one hour before doing resistance training (at 4 p.m.).

Category

Other

4

Description

Supplement group: participants of this group consumed one Epicatechin capsule daily (1mg/kg/day) with 200 ml water, at 4 p.m. for 8 weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Tehran

Full name of responsible person

Alireza Ghardashi Afousi

Street address

Faculty of Physical Education and Sport Sciences, after the intersection of Jalal Al Ahmad, between 15th and 16th Street, North Kargar Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Alireza Ghardashi Afousi

Street address

Faculty of Physical Education and Sport Sciences, after the intersection of Jalal Al Ahmad, between 15th and 16th Street, North Kargar Street

City

Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
University of Tehran
Full name of responsible person
Alireza Ghardashi Afousi
Position
PhD student of exercise physiology
Other areas of specialty/work
Street address
Faculty of Physical Education and Sport Sciences,
after the intersection of Jalal Al Ahmad, between 15th
and 16th Street, North Kargar Street
City
Tehran
Postal code
Phone
+98 21 8835 1740
Fax
Email
ghardashi.a@ut.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Tehran
Full name of responsible person
Abbasali Gaeini
Position

University of Tehran Professor
Other areas of specialty/work
Street address
Faculty of Physical Education and Sport Sciences,
after the intersection of Jalal Al Ahmad, between 15th
and 16th Street, North Kargar Street
City
Tehran
Postal code
Phone
+98 21 8835 1740
Fax
Email
aagaeini@ut.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
University of Tehran
Full name of responsible person
Alireza Ghardashi Afousi
Position
PhD student of exercise physiology
Other areas of specialty/work
Street address
Faculty of Physical Education and Sport Sciences,
after the intersection of Jalal Al Ahmad, between 15th
and 16th Street, North Kargar Street
City
Tehran
Postal code
Phone
+98 21 8835 1740
Fax
Email
ghardashi.a@ut.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty