Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of resistance training and Soy milk Consumption on Skeletal Muscle Regulatory Markers in the Elderly

Protocol summary

Study aim
The Effect of a long period resistance training and Soy milk Consumption on Skeletal Muscle Regulatory Markers in the Elderly

Design
Volunteers first register and then subjects selected purposefully based on inclusion criteria, and randomly divided into Four groups of resistance training, Soy milk, resistance training + Soy milk and control.

Settings and conduct
Subjects in resistance training groups and Soy milk + resistance training groups performed the resistance training protocol for twelve weeks (3 days per week). Also subjects in the Soy milk and resistance training + Soy milk groups consumed 240mL of Soy milk daily for twelve weeks. Blood sampling were measured in several stages.

Participants/Inclusion and exclusion criteria
Inclusion criteria consisted: Non-athletic older adults aged 60-80 years, without the experience of regular physical activity in the last year. The exclusion criteria: the history of special diseases; allergy to Soy milk; unwillingness; muscular or joint injuries.

Intervention groups
Four groups of resistance training, Soy milk, resistance training + Soy milk and control

Main outcome variables
Effect of resistance training and Soy milk consumption on GDF-11; GDF-15; Myostatin; Follistatin; Activin A

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190731044398N3**
Registration date: **2019-09-07, 1398/06/16**
Registration timing: **retrospective**
Last update: **2019-09-07, 1398/06/16**
Update count: **0**

Registration date
2019-09-07, 1398/06/16

Registrant information

Name
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Name of organization / entity
Ferdowsi University of Mashhad

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
2018-06-22, 1397/04/01

Actual recruitment end date
2018-09-23, 1397/07/01

Trial completion date
2018-09-23, 1397/07/01

Scientific title
The Effect of resistance training and Soy milk Consumption on Skeletal Muscle Regulatory Markers in the Elderly

Public title
The Effect of a long period resistance training and Soy milk Consumption on Skeletal Muscle Regulatory Markers in the Elderly

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Non-athletic older adults aged 60-80 years Without the experience of regular physical activity in the last year The exclusion criteria

Exclusion criteria:

The history of special diseases Allergy to Soy milk Unwillingness Muscular or joint injuries

Age

From **60 years** old to **80 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, simple randomization method with random number Table method was used. This table contains a bunch of numbers that are randomly drawn in the form of a table without a specific pattern and order. The numbers directions(Left, right, up, down) were first determined by the researcher to read the numbers and then the numbers were considered for different research groups. In the next step, the researcher randomly placed on one of the numbers and moved in the present direction and recorded the numbers for that direction in the target group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, participants are unaware of the group assigned to themselves and other participants. A separate workout hour is considered for each intervention group. Experts in laboratory analysis are also unaware of the type of intervention and the participating groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Physical Education and Sport Sciences

Street address

Impasse 5, district 7, Tehran, Iran

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Province

Tehran

Postal code

1587958711

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.SSRC.REC.1398.062

Health conditions studied

1

Description of health condition studied

Healthy

ICD-10 code

Z00

ICD-10 code description

Persons encountering health services for examination and investigation

Primary outcomes

1

Description

Serum levels of GDF-11

Timepoint

Before and 6 and 12 weeks after intervention

Method of measurement

Blood sampling and using ELISA method

2

Description

Serum levels of GDF-15

Timepoint

Before and 6 and 12 weeks after intervention

Method of measurement

Blood sampling and using ELISA method

3

Description

Serum levels of Myostatin

Timepoint

Before and 6 and 12 weeks after intervention

Method of measurement

Blood sampling and using ELISA method

4

Description

Serum levels of Follistatin

Timepoint

Before and 6 and 12 weeks after intervention
Method of measurement
Blood sampling and using ELISA method

5

Description
Serum levels of Activin A
Timepoint
Before and 6 and 12 weeks after intervention
Method of measurement
Blood sampling and using ELISA method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the training group performed 12 weeks and each week 3 sessions of resistance training.
Category
Other

2

Description
Intervention group: the Soy milk group consumed 240 ml of Soy milk for 12 weeks each day.
Category
Other

3

Description
Intervention group: the training + Soy milk group performed resistance training program for 12 weeks and 3 sessions per week and consumed 240 ml Soy milk daily.
Category
Other

4

Description
Control group: the control group did not perform resistance training and did not consume Soy milk.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Tehran
Full name of responsible person
Babak Hooshmand Hoghadam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor For Research, Ferdowsi University
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?
No
Title of funding source
personal
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Ferdowsi University of Mashhad
Full name of responsible person
Babak Hooshmand Hoghadam
Position

PhD student
Latest degree
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Other areas of specialty/work
Physiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be 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
Personal information of patients is confidential. But access to the research method and the information obtained from the research is not a problem
When the data will become available and for how long
After printing in a journal
To whom data/document is available
All students and enthusiasts
Under which criteria data/document could be used
In order to use data to carry out research work in this area
From where data/document is obtainable
The authors of this article b.hooshmand.m@gmail.com
What processes are involved for a request to access data/document
By sending email the author will work with the applicant as soon as possible
Comments