Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Resistance Training Combined with Vitamin D Supplementation on IGF-1 Levels and Neuromuscular Junction Function (Anti-Acetylcholine Receptor Antibody) in Elderly Women with Sarcopenia

Protocol summary

Study aim

The aim of this study was to investigate the effect of a period of resistance training combined with vitamin D supplementation on serum levels of insulin-like growth factor 1, neuromuscular receptor function based on acetylcholine receptor antibody levels, and muscle function indices including handgrip strength, chair test, and walking speed in elderly women with sarcopenia.

Design

This was a quasi-experimental study with a 2x2 factorial design and a control group. 40 elderly women with sarcopenia were randomly assigned to four parallel groups (resistance training + vitamin D, resistance training, vitamin D, and control) in a block design. The study was unblinded and lacked a clinical trial phase.

Settings and conduct

This quasi-experimental study with a pretest-posttest design and control group was conducted in Aligudarz city in 2016 on 40 elderly women with sarcopenia.

Participants/Inclusion and exclusion criteria

Advanced or unstable cardiovascular disease Uncontrolled blood pressure (above 160/100 mmHg) Untreated thyroid disorders Kidney failure Vitamin D supplementation in the last 3 months Any medical contraindication to resistance training Severe mobility limitations or inability to perform functional tests Active inflammatory or autoimmune diseases Use of medications that affect muscle and bone metabolism (such as corticosteroids) Unwillingness or inability to provide informed consent

Intervention groups

Resistance training group with vitamin D supplementation Resistance training group Vitamin D supplementation group Control group

Main outcome variables

Serum IGF-1 levels; serum Anti-AChR Ab levels (neuromuscular receptor function); muscle function indices (hand grip strength, 30-second chair test, and walking speed)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260621069896N1**
Registration date: **2026-06-23, 1405/04/02**
Registration timing: **retrospective**

Last update: **2026-06-23, 1405/04/02**
Update count: **0**

Registration date

2026-06-23, 1405/04/02

Registrant information

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Hossein Barzegari Marvast

Name of organization / entity

Yazd University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-12, 1405/02/22

Expected recruitment end date

2026-05-21, 1405/02/31

Actual recruitment start date

2026-05-26, 1405/03/05

Actual recruitment end date
2026-06-05, 1405/03/15
Trial completion date
2026-08-11, 1405/05/20

Scientific title
The Effect of Resistance Training Combined with Vitamin D Supplementation on IGF-1 Levels and Neuromuscular Junction Function (Anti-Acetylcholine Receptor Antibody) in Elderly Women with Sarcopenia

Public title
The effect of resistance training combined with vitamin D supplementation on IGF-1 levels, neuromuscular function, and muscle strength in elderly women with sarcopenia
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Elderly women with sarcopenia according to EWGSOP2 criteria Age 60-70 years Resident of Aligudarz city Ability to participate in resistance training program (without severe movement restriction) No vitamin D supplementation in the last 3 months Informed consent to participate in the study
Exclusion criteria:
Advanced or unstable cardiovascular disease Uncontrolled blood pressure (above 160/100 mmHg) Untreated thyroid disorders Renal failure (Cr > 1.5 mg/dL or GFR < 60) Vitamin D supplementation in the last 3 months Any medical contraindication to resistance training Severe mobility limitations or inability to perform functional tests Active inflammatory or autoimmune diseases (such as rheumatoid arthritis) Use of medications that affect bone and muscle metabolism (such as corticosteroids) Unwillingness or inability to provide informed consent
Age
From **60 years** old to **70 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
After assessing the inclusion and exclusion criteria, eligible participants were randomly assigned to four groups (resistance training + vitamin D, resistance training, vitamin D, and control). The randomization method was block randomization with a block size of 4, which was performed using Excel software to maintain a balance in the number of individuals in each group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features
This study is a quasi-experimental study with a pretest-posttest design and a control group and a 2x2 factorial design. The two intervention factors included “resistance training” (two levels: yes/no) and “vitamin D supplementation” (two levels: yes/no). Eligible participants were randomly assigned to four parallel groups (resistance training + vitamin D, resistance training alone, vitamin D alone, and control). The intervention duration was 8 weeks and the main objective was to evaluate the main effect of each intervention as well as the interaction effect (synergistic effect) between resistance training and vitamin D on IGF-1 levels, neuromuscular junction function, and muscle performance indices.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
yazd university
Street address
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۸۹۱۵۸۱۸۴۱۱
Approval date
2026-04-29, 1405/02/09
Ethics committee reference number
IR.YAZD.REC.1405.016

Health conditions studied

1

Description of health condition studied
Sarcopenia
ICD-10 code
M62.84
ICD-10 code description
کاهش توده و قدرت عضلانی مرتبط با سن

Primary outcomes

1

Description
Serum IGF-1 levels
Timepoint

They were measured at two time points: pre-test (48 to 72 hours before the start of the intervention) and post-test (48 to 72 hours after the completion of the 8-week intervention).

Method of measurement

They were measured using enzyme-linked immunosorbent assay (ELISA) and special kits. Insulin-like growth factor type 1 levels were measured with a German Mediagnosis kit.

2

Description

Anti-AChR Ab

Timepoint

They were measured at two time points: pre-test (48 to 72 hours before the start of the intervention) and post-test (48 to 72 hours after the completion of the 8-week intervention).

Method of measurement

They were measured using enzyme-linked immunosorbent assay (ELISA) and special kits. Acetylcholine receptor antibody levels were measured with a Hanyin Biotech China kit.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Control group:Participants in this group did not receive any training intervention or supplementation and continued their daily activities.Intervention group 1 (resistance training with vitamin D supplementation):The intervention consisted of two concurrent parts:Resistance training: 8 weeks, 3 sessions per week (non-consecutive days), at an intensity of 60-75% of one repetition maximum (1RM), including 8 main movements (4 upper body movements and 4 lower body movements) in 3 sets of 10-12 repetitions with 1-2 minutes of rest between sets. Sessions were performed under the direct supervision of an exercise physiologist.Vitamin D supplementation: Oral intake of 50,000 IU of vitamin D3 (cholecalciferol) weekly for 8 weeks.Intervention group 2 (resistance training alone):Exactly the same resistance training protocol as group 1 (8 weeks, 3 sessions per week, 60-75% of 1RM, 8 movements, 3 sets of 10-12 repetitions) without receiving any supplementation.Third intervention group (vitamin D supplementation alone):Oral intake of 50,000 IU of vitamin D3 (cholecalciferol) weekly for 8 weeks, without performing a resistance training program.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers and Elderly Nursing Homes of Aligudarz City

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zahra mosayebi

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Sponsors / Funding sources

1

Sponsor

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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

yazd University

Proportion provided by this source

10

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
yazd university
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Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the sensitive nature of personal health data of elderly participants and ethical considerations regarding privacy and confidentiality, there is no plan to share individual participant data.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Study Protocol and Final Clinical Study Report
When the data will become available and for how long
The study protocol and final clinical study report will be available starting 6 months after the publication of the main results of the study.
To whom data/document is available
Qualified researchers and scientists affiliated with academic or research institutions.
Under which criteria data/document could be used
The documents may be used for academic and scientific purposes, including meta-analyses, secondary research, and educational uses, provided that the original study is properly cited. Commercial use is not permitted.
From where data/document is obtainable
Requests should be sent to the corresponding author: Dr. Hossein Barzegari Marvast, Yazd University, via email: h.barzegari@staff.yazd.ac.ir
What processes are involved for a request to access data/document
The requester must submit a formal written request including their affiliation, research proposal, and intended use of the documents. The corresponding

author will review the request within 4-6 weeks. If approved, the documents will be sent via secure email after signing a data use agreement.

Comments