

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effects of Resistance Training With and Without Blood Flow Restriction on Follistatin and IGF-1 Levels in Male Students

Protocol summary

Study aim

To investigate the effects of resistance training with and without blood flow restriction on follistatin levels, IGF-1, body fat percentage, and muscular strength in male students

Design

This study was a randomized, parallel, single-blind clinical trial conducted on 45 male students. Participants were randomly assigned into three equal groups (resistance training with blood flow restriction, traditional resistance training, and control) using a random number table and the G-Power software. The sample size was calculated using G-Power, and the trial aimed to evaluate the effects of the interventions on follistatin, IGF-1, body fat percentage, and muscular strength. The trial was conducted in the implementation phase and adhered to clinical trial principles.

Settings and conduct

The study was conducted at Shahrekord Azad University gym and a specialized

Participants/Inclusion and exclusion criteria

Inclusion criteria included males aged 20 to 25 years with a BMI of 20 to 25 kg/m², no regular physical activity in the past six months, and general health confirmed by a physician. Exclusion criteria included cardiovascular diseases, chronic conditions such as diabetes or kidney failure, use of medications or supplements affecting hormones, and physical or psychological limitations preventing participation in the exercises

Intervention groups

The study included three groups: the first group performed blood flow restriction resistance training (20-30% 1RM), the second group performed traditional resistance training (70-80% 1RM), and the third group served as the control group without exercise intervention.

Main outcome variables

Follistatin levels; IGF-1 levels; body fat percentage; muscular strength (leg press and bench press).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241205063953N2**

Registration date: **2025-02-09, 1403/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2025-02-09, 1403/11/21**

Update count: **0**

Registration date

2025-02-09, 1403/11/21

Registrant information

Name

akram jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 547 9267

Email address

jafari.akm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-29, 1403/11/10

Expected recruitment end date

2025-03-30, 1404/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Resistance Training With and Without Blood Flow Restriction on Follistatin and IGF-1 Levels in Male Students	
Public title	Blood Flow Restriction Resistance Training, Follistatin, and IGF-1
Purpose	Other
Inclusion/Exclusion criteria	Inclusion criteria: Male aged 20 to 25 years Body Mass Index (BMI) between 20 and 25 kg/m² No medical contraindications for resistance training with blood flow restriction No regular physical activity in the past six months General health confirmed by a physician, including cardiovascular and blood pressure assessment No use of specific medications or supplements affecting sports performance or hormones Exclusion criteria: History of cardiovascular disease or uncontrolled hypertension Presence of chronic conditions such as diabetes, kidney, or liver failure Physical or musculoskeletal limitations preventing resistance training Use of medications affecting hormones or metabolism Consumption of sports supplements or anabolic steroids Recent injury or surgery affecting physical performance
Age	From 20 years old to 25 years old
Gender	Male
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 45
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization will be used to allocate participants into three groups. A random number table will be utilized for this purpose. The random number table will be obtained from a standard source (such as statistical software or reference books on randomization). Each group will be assigned a code: Group 1 (traditional resistance training), Group 2 (resistance training with blood flow restriction), Group 3 (control). To generate the sequence, random numbers will be read from the table in order. Each number will be assigned sequentially to one of the three groups. The randomization sequence will be prepared confidentially and placed in sealed and numbered envelopes. The envelope numbers will correspond to the participant numbers (based on the order of entry into the study). The staff responsible for participant enrollment will not have access to the content of the envelopes or the group allocation sequence. Each participant, after being confirmed as eligible for the study, will receive a numbered envelope based on their order of entry (e.g., the first participant will receive envelope 1, the second
	participant envelope 2, and so on). The envelope number will indicate the group allocation for that participant. The randomization and allocation process will be conducted by an independent individual (unrelated to data analysis or intervention implementation) to ensure impartiality. All envelopes will remain sealed until the allocation process is complete.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Research Ethics Committee of Islamic Azad University, Shahrekord Branch
Street address	Islamic Azad University, Rahmatieh, Shahrekord Branch, Shahrekord, Iran
City	Shahrekord
Province	Chahar-Mahal-va-Bakhtiari
Postal code	8817630003
Approval date	2025-01-09, 1403/10/20
Ethics committee reference number	IR.IAU.SHK.REC.1403.336
Health conditions studied	
<u>1</u>	
Description of health condition studied	Exercise
ICD-10 code	Z00.3
ICD-10 code description	Encounter for examination for adolescent development state
Primary outcomes	
<u>1</u>	
Description	follistatin
Timepoint	It will be measured 48 hours before the start and 48

hours after the end of the intervention

Method of measurement
Measured using the enzyme-linked immunosorbent assay (ELISA) method with kits from R&D Systems, USA.

2

Description
IGF-1 levels

Timepoint
It will be measured 48 hours before the start and 48 hours after the end of the intervention

Method of measurement
Measured using the ELISA method with kits from Mediagnost, Germany

3

Description
Body fat percentage

Timepoint
It will be measured 48 hours before the start and 48 hours after the end of the intervention

Method of measurement
Measured using a bioelectrical impedance analysis device, Olympia 3.3, manufactured in South Korea

4

Description
Muscular strength (leg press and bench press)

Timepoint
It will be measured 48 hours before the start and 48 hours after the end of the intervention

Method of measurement
Assessed through the one-repetition maximum (1RM) test and calculated using the Brzycki formula.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants will train for eight weeks, three sessions per week. Training intensity will be set at 20-30% of one-repetition maximum (1RM), with specialized cuffs applied to the exercising limbs to partially restrict blood flow. Cuff pressure will be adjusted based on individual systolic blood pressure (120-160 mmHg) and increased by 10% every two weeks. Exercises include leg press, leg curl, biceps curl, triceps extension, and knee extension, performed in four sets each.

Category
N/A

2

Description

Intervention group: Participants will train for eight weeks, three sessions per week. Training intensity will be set at 70-80% of 1RM without any blood flow restriction. Exercises will be identical to Intervention Group 1, including leg press, leg curl, biceps curl, triceps extension, and knee extension, performed in four sets each

Category
N/A

3

Description
Control group: Participants in this group will not receive any exercise intervention and will continue their regular daily activities.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University, Shahrekord Branch

Full name of responsible person
Farshid Khairi

Street address
Rahmatieh, Islamic Azad University, Shahrekord Branch, Shahrekord, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Farshid Kahiri

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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
Islamic Azad 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
Islamic Azad University

Full name of responsible person
Akram Jafari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

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Rahmatieh, Islamic Azad University, Shahrekord Branch, Shahrekord, Iran

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Person responsible for scientific inquiries

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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Raw data related to the primary outcome variables (follistatin levels, IGF-1 levels, body fat percentage, and muscular strength) will be shared after anonymizing participants' personal information. The data will be

provided in Excel files and will be accessible solely for research purposes. Access requests must be sent via email to the corresponding author and will be granted upon approval by the Research Ethics Committee of Islamic Azad University, Shahrekord Branch.

When the data will become available and for how long

Access to the data and documents will begin 6 months after the publication of results in a peer-reviewed scientific journal and will remain available for 2 years.

To whom data/document is available

The data and documents will only be accessible to researchers affiliated with academic and scientific institutions. Applicants must provide their institutional affiliation and specify their research purpose.

Under which criteria data/document could be used

The data will be used solely for research and scientific analysis and cannot be used for commercial or personal purposes. Applicants must submit a research proposal, adhere to ethical research principles, and sign an

agreement not to share the data. Access will be granted upon approval by the Research Ethics Committee of Islamic Azad University, Shahrekord Branch.

From where data/document is obtainable

Applicants can send their requests to the corresponding author, Naser Alimardani, via email at Jafari.akm@gmail.com. For coordination and follow-up, they can also contact him at +98 9125479267. Postal address: Department of Physical Education, Islamic Azad University, Shahrekord Branch, Shahrekord, Chaharmahal and Bakhtiari, Iran.

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

The applicant must email their research proposal, study objectives, and institutional affiliation to the corresponding author. After review and approval by the ethics committee, the applicant signs an ethical agreement, and the data is shared within 2 to 4 weeks via email or a secure platform.

Comments