Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative analysis of the impact of two resistance training loading protocols, combined with Tribulus supplementation, on hormonal responses and muscle strength in young athletes.

Protocol summary

Study aim

Examine the impact of two resistance training protocols along with supplementation, on testosterone, cortisol, lipid profiles, and maximal strength of young athletes.

Design

This research involves a clinical trial design that includes four groups, with each group comprising a sample of 12 participants.

Settings and conduct

The performance assessment takes place in a gym setting utilizing fitness equipment, while blood tests are conducted in a laboratory. Blood samples are collected in a fasting state prior to the initiation of training and supplement consumption, with a follow-up measurement occurring after an 8-week period.

Participants/Inclusion and exclusion criteria

A group of 48 male volunteers, aged between 25 and 45, will be selected to participate in this study. To qualify for inclusion, participants must have consistently engaged in physical activity over the past year, must be free from musculoskeletal injuries or particular medical conditions, and must not be using any other dietary supplements. On the other hand, the exclusion criteria include voluntary withdrawal from the study, the development of physical injuries or specific illnesses, and the absence from more than three sessions of the exercise interventions.

Intervention groups

Participants will be randomly assigned to one of four experimental groups. Each group will consist of 12 individuals, totaling 48 participants. The groups will include: one focused on strength training at 70% of maximum strength to failure, another utilizing pyramid loading for strength training, a third group engaging in strength training at 70% of maximum strength while receiving supplements, and a fourth group combining pyramid loading with supplements.

Main outcome variables

Testosterone and cortisol hormones; Muscle Strength; Body Composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250203064626N1**
Registration date: **2025-09-07, 1404/06/16**
Registration timing: **retrospective**

Last update: **2025-09-07, 1404/06/16**
Update count: **0**

Registration date

2025-09-07, 1404/06/16

Registrant information

Name

Shahab Azari

Name of organization / entity

Faculty of Sport Sciences of University of Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 913 084 8414

Email address

shaahabazari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-02, 1404/03/12

Expected recruitment end date

2025-08-21, 1404/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative analysis of the impact of two resistance training loading protocols, combined with Tribulus supplementation, on hormonal responses and muscle strength in young athletes.

Public title

The simultaneous effect of Tribulus supplementation and resistance training on muscle strength of athletes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Engagement in consistent physical exercise over the previous year. Avoid musculoskeletal injuries or particular illnesses. Refrain from utilizing additional supplements.

Exclusion criteria:

Participants have the option to withdraw from the plan at any time. Sustaining physical harm and acquiring specific illnesses. Absence from over three sessions.

Age

From **25 years** old to **45 years** old

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the researcher and participants will not be aware of the supplement or placebo in a double-blind design.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee at the University of Isfahan

Street address

University Street, Isfahan

City

Isfahan

Province

Isfehan

Postal code

81746-73441

Approval date

2025-03-01, 1403/12/11

Ethics committee reference number

IR.UI.REC.1403.188

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Cortisol

Timepoint

The assessment period will occur prior to the initiation of the intervention and again following eight weeks of training and supplementary interventions.

Method of measurement

Measurements are conducted utilizing specialized kits and the ELISA technique.

2

Description

Testosterone

Timepoint

The assessment period will occur prior to the initiation of the intervention and again following eight weeks of training and supplementary interventions.

Method of measurement

Measurements are conducted utilizing specialized kits and the ELISA technique.

3

Description

Muscle Strength

Timepoint

The assessment period will occur prior to the initiation of the intervention and again following eight weeks of training and supplementary interventions.

Method of measurement
It is performed using a fitness machine and a dynamometer.

4

Description
Body Fat Percentage
Timepoint
The assessment period will occur prior to the initiation of the intervention and again following eight weeks of training and supplementary interventions.
Method of measurement
Body fat percentage is determined with a body composition measuring device (In-Body).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: will perform resistance exercises with a new protocol.
Category
N/A

2

Description
Intervention Group 2: will perform a traditional resistance training protocols.
Category
N/A

3

Description
Control group: participants who did not receive training and were given a placebo.
Category
Placebo

4

Description
Intervention group 3: will perform a resistance training protocol combined with Tribulus supplementation.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The University of Isfahan
Full name of responsible person
Shahab Azari
Street address
Daneshgah
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۴۱
Phone
+98 913 084 8414
Fax
Email
shaahabazari@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Isfahan
Full name of responsible person
Babak Safari
Street address
University Street
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۴۱
Phone
+98 31 3793 2171
Email
b_saffari@ase.ui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Isfahan
Proportion provided by this source
40
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
University of Isfahan
Full name of responsible person
Vazgen Minasian
Position

Professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise Physiology
Street address
University Street
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۴۱
Phone
+98 31 3736 2369
Email
v.minasian@spr.ui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Isfahan
Full name of responsible person
Vazgen Minasian
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise Physiology
Street address
University Street
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۴۱
Phone
+98 31 3793 2369
Email
v.minasian@spr.ui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
The University of Isfahan
Full name of responsible person
Shahab Azari
Position
MSc student
Latest degree
Master
Other areas of specialty/work
Sport Nutrition
Street address
No.24, West Kargar Alley, Farabi Street, Ghadir Blvd., Sepahan shahr
City
Isfahan
Province
Isfehan
Postal code
8179965387
Phone
+98 913 084 8414
Email
shaahabazari@gmail.com

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
Access to the documents can be granted following the publication of the article, contingent upon a request from researchers and the acquisition of permission from the University of Isfahan.
When the data will become available and for how long
Access to documents is available for at least 3 months after the publication of the articles resulting from this thesis.
To whom data/document is available
Only academic researchers are allowed to access the documents.
Under which criteria data/document could be used
Documentation is available after the publication of the article and upon request from researchers for research purposes and with permission from the University of Isfahan.
From where data/document is obtainable
To receive documentation, please contact the University of Isfahan's Research Affairs and researchers.
What processes are involved for a request to access data/document
To receive the documents, a written request must be submitted and action must be taken through the university's administrative affairs.
Comments
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