

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effects of two resistance and concurrent training programs with high protein diets on physical performance, biochemical markers, and body composition in resistance trained males

Protocol summary

Study aim

To study the effects of a 16-week different resistance and concurrent training programs with two types of high-protein diets on muscle strength, power, endurance, biochemical markers in adipose tissue, liver and kidney, maximum oxygen consumption, and body composition in resistance trained males

Design

Measurements will be collected at baseline, week 8, and after 16 weeks. Participants first will complete four preliminary testing days: on the first visit, questionnaires will be assessed; on the second visit, blood draw and body composition will be performed; on the third visit, maximal aerobic capacity (Vo₂max) and performance tests will be performed.; on the fourth visit, participants will complete chest press and leg press 1RM, muscular endurance tests (75% 1RM), and muscular power.

Settings and conduct

After randomization and pre-testing, training protocols will be performed in the gym.

Participants/Inclusion and exclusion criteria

In terms of health status; Healthy and having no specific problems or diseases. Have an age range between 18 and 35 years. Male participants. Have a history of resistance training for at least 1 year on a regular basis (at least three training sessions per week). Have not used anabolic steroids and peptides in the past year. Being free from musculoskeletal disorders. Exclusion criteria: Musculoskeletal injuries Not following the prescribed diet Anabolic steroid injection Contributing in exercises out of prescribed ones Lack of inner desire to carry on exercise or diet intervention

Intervention groups

Resistance training + 1.6 g/kg/day
Resistance training + 3.2 g/kg/day
Concurrent training + 1.6 g/kg/day
Concurrent training + 3.2 g/kg/day

Main outcome variables

Muscle strength, strength, endurance, biochemical markers in adipose tissue, liver and kidney, maximum oxygen consumption, and body composition (body fat percentage , lean mass, BMC, BMD, etc.)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191204045612N2**

Registration date: **2022-01-31, 1400/11/11**

Registration timing: **prospective**

Last update: **2022-01-31, 1400/11/11**

Update count: **0**

Registration date

2022-01-31, 1400/11/11

Registrant information

Name

Sajjad Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3824 2314

Email address

smoradi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-09, 1400/11/20

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of two resistance and concurrent training programs with high protein diets on physical performance, biochemical markers, and body composition in resistance trained males

Public title
Comparison of two high protein diets and physical activity on physical performance, biochemical markers and body composition in resistance-trained males

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Have a history of resistance training for at least 1 year on a regular basis (at least three training sessions per week). All the participants will be males. Having a normal sleep state. In terms of health status; Healthy and have no specific problems or diseases. Between the age of 18 to 35 years.
Exclusion criteria:
Musculoskeletal injuries Not following the prescribed diet Anabolic steroid injection Contributing in exercises out of prescribed ones Lack of inner desire to carry on exercise or diet intervention

Age
From **18 years** old to **35 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method using random number table is used. This method first uses a random number table, which is a set of numbers that have no pattern or order and which is completely generated. The researcher divides these numbers randomly between the intervention groups (both resistance training groups are the controls of concurrent training groups). With the presence of clients, the researcher begins to read the numbers in the specified order. Each participant receives its own number and is randomly assigned to either resistance training groups (2 groups: resistance training with 1.6 g/kg/day of protein and resistance training with 3.2 g/kg/day of protein) or concurrent training groups (2 groups: concurrent training + 1.6 g/kg/day of protein and concurrent training + 3.2

g/kg/day of protein).

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind study. Since the researcher and the participants should not be aware of the group and the amount of protein consumed, a third person who is not aware of the objectives of the study will do the group assignment and protein recommendation. Also, the third person will codify them randomly and then provide the researcher with the code. It should be noted that all participants will be informed about the research and objectives, but will not be given information about which group they belong to. Data analysis will also be performed by an out-of-group biostatistics specialist who is not aware of the participants and group assignment.

Placebo
Not used

Assignment
Parallel

Other design features
Two resistance training groups will be the control groups for concurrent training groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of university of Isfahan

Street address

Isfahan, Azadi Square, University of Isfahan

City

Isfahan

Province

Isfahan

Postal code

8114673441

Approval date

2022-01-26, 1400/11/06

Ethics committee reference number

IR.UI.REC.1400.098

Health conditions studied

1

Description of health condition studied

Body composition, muscular and cardiovascular adaptation in resistance-trained males

ICD-10 code

Y93.B

ICD-10 code description

Activities involving other muscle strengthening exercises

Primary outcomes

1

Description

Muscle strength

Timepoint

Pre-test, week 8 and week 17 (after 16 weeks of training)

Method of measurement

1RM tests for chest and leg press

2

Description

Power

Timepoint

Pre-test, week 8 and week 17 (after 16 weeks of training)

Method of measurement

Wingate test for upper and lower body

3

Description

Biochemical markers for adipose tissue, liver and kidney.

Timepoint

Pre-test, week 8 and week 17 (after 16 weeks of training)

Method of measurement

Measurements with laboratory kits

4

Description

Vo₂max

Timepoint

Pre-test, week 8 and week 17 (after 16 weeks of training)

Method of measurement

Through Bruce test

5

Description

Muscular endurance

Timepoint

Pre-test, week 8 and week 17 (after 16 weeks of training)

Method of measurement

Through 75% of 1RM for chest and leg press

6

Description

Body composition

Timepoint

Pre-test, week 8 and week 17 (after 16 weeks of training)

Method of measurement

Through DXA, 3D scan, and BIA

Secondary outcomes

1

Description

The relationship between lean mass and muscular adaptation

Timepoint

At the end of the study

Method of measurement

With statistical analysis methods

2

Description

Comparison between DXA, BIA, and 3D scan

Timepoint

Pre-test, week 8 and week 17

Method of measurement

Hologic Discovery, Inbody device, and 3d scan

Intervention groups

1

Description

Intervention group 1: Resistance training + high protein diet (1.6 g/kg/day). In this group, participants will train for 4 sessions per week for 16 weeks. It should be noted that resistance training in the two groups of resistance training will be the same and there will be only a difference in the dose of protein consumed. Regarding testing sessions for all intervention groups, on the first visit, questionnaires will be assessed; on the second visit, blood draw (after 48 hours of rest and 8 overnight sleep), and body composition will be performed; on the third visit, maximal aerobic capacity (Vo₂max) and performance tests will be performed; on the fourth visit, participants will complete chest press and leg press 1RM, muscular endurance tests (75% of 1RM), and muscular power. After completing the pre-test process, the participants will be visited by a nutritionist and will be informed about the nutritional conditions of the study.

Category

N/A

2

Description

Intervention group 2: Resistance training + high protein diet (3.2 g/kg/day). In this group, participants will also train for 4 sessions per week for 16 weeks. It should be noted that resistance training in the two groups of resistance training will be the same and there will be only a difference in the dose of protein consumed.

Category

N/A

3

Description

Intervention group 3: Concurrent training + high protein diet (1.6 g/kg/day). In this group, participants will also train for 4 sessions per week for 16 weeks. It should be noted that resistance training in the two groups of concurrent training will be the same and there will be only a difference in the dose of protein consumed. In this group, participants will perform resistance training at the beginning of the session and then will perform endurance training.

Category

N/A

4**Description**

Intervention group 3: Concurrent training + high protein diet (3.2 g/kg/day). In this group, participants will also train for 4 sessions per week for 16 weeks. It should be noted that resistance training in the two groups of concurrent training will be the same and there will be only a difference in the dose of protein consumed. In this group, participants will perform resistance training at the beginning of the session and then will perform endurance training.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Nuclear research center

Full name of responsible person

Dr. Ramin Sadeghi

Street address

Koohsangi street

City

Mashhad

Province

Razavi Khorasan

Postal code

1564563897

Phone

+98 51 3838 3363

Email

sadeghir@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of Isfahan

Full name of responsible person

Professor Mehdi Kargarfard

Street address

Isfahan, Azadi Sq, University of Isfahan

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۴۱

Phone

+98 31 3793 2128

Fax

+98 31 3668 7396

Email

m.kargarfard@spr.ui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

University of Isfahan

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**

University of Isfahan

Full name of responsible person

Reza Bagheri

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiology

Street address

Shariati St, Hatami 7

City

Mashhad

Province

Razavi Khorasan

Postal code

9189763902

Phone

+98 51 3521 4034

Email

will.fivb@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of Isfahan

Full name of responsible person

Reza Bagheri

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiology

Street address

Shariati st, Hatami 7

City

Mashhad

Province

Razavi Khorasan

Postal code

9189763902

Phone

+98 51 3521 4034

Email

will.fivb@yahoo.com

Province

Razavi Khorasan

Postal code

9189763902

Phone

+98 51 3521 4034

Email

will.fivb@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

University of Isfahan

Full name of responsible person

Reza Bagheri

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiology

Street address

Shariati st, Hatami 7

City

Mashhad

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable