

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of 12 weeks of interval training with different intensity on serum levels of Fibroblast growth factor 21, Myostatin and Irisin in obese and overweight men

Protocol summary

Study aim

The effect of 12 weeks of interval training with different intensities on serum levels of Fibroblast growth factor 21, Myostatin and Irisin in overweight and obese Men

Design

12-week training program in experimental groups 1 to 3 included heavy running from 88 to 93, a moderate intensity of 73 to 78, and a light intensity of 58 to 63 percent of maximal heart rate and three sessions per week. A sample of 47 people who were randomly (The method of tracking) assigned to 4 groups(experimental groups:12, control group:11).Before and after the training period, Irisine, FGF21 and Mayostatin serum samples were taken from all subjects in fasting state., Anthropometric measurements were also performed. clinical trial type: randomized clinical trial with control group

Settings and conduct

The training program is 12 weeks and three sessions a week. The place of the study is the sports hall in Bojnurd city. Subjects were running in the designated range of heart rates by attending at the gym (6 o'clock).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Young men (20,30) years, Having body mass index greater than 25 kg,m2 Exclusion criteria: Use of medication,Tobacco use , Having Chronic diseases, Having Regular physical activity

Intervention groups

Three intensities of interval training 1. Low (58,63%of maximal heart rate) 2. Medium (73,78%of maximal heart rate) 3. Heavy (88,93% of maximal heart rate) 4. Control (Lack of exercise)

Main outcome variables

Irisin; Myostatin; FGF21

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190719044269N1**

Registration date: **2020-03-30, 1399/01/11**

Registration timing: **retrospective**

Last update: **2020-03-30, 1399/01/11**

Update count: **0**

Registration date

2020-03-30, 1399/01/11

Registrant information

Name

Saeed Ramezani

Name of organization / entity

The University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 58 3232 3963

Email address

rsaeid92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-28, 1398/07/06

Expected recruitment end date

2019-10-09, 1398/07/17

Actual recruitment start date

2019-09-28, 1398/07/06

Actual recruitment end date

2019-10-09, 1398/07/17

Trial completion date

2020-01-04, 1398/10/14

Scientific title

The effect of 12 weeks of interval training with different intensity on serum levels of Fibroblast growth factor 21, Myostatin and Irisin in obese and overweight men

Public title

The effect of interval training with different intensities on weight loss and brown adipose tissue markers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Young men (20,25) years Having a body mass index greater than 25 kg,m 2

Exclusion criteria:

Use of medication Tobacco use Having Chronic diseases Having Regular physical activity

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: **50**

Actual sample size reached: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random method, Individual randomization, The method of tracking was used. Each name dropped out of the container in light, medium, heavy and control groups, respectively

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Enghlab Square

City

Tehran

Province

Tehran

Postal code

1417414418

Approval date

2019-09-24, 1398/07/02

Ethics committee reference number

IR.UT.SPORT.REC.1398.051

Health conditions studied

1

Description of health condition studied

Obesity and overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Fibroblast growth factor 21(FGF21)

Timepoint

First and 12 weeks later

Method of measurement

ELISA laboratory method

2

Description

Myostatin

Timepoint

First and 12 weeks later

Method of measurement

ELISA laboratory method

3

Description

Irisin

Timepoint

First and 12 weeks later

Method of measurement

ELISA laboratory method

Secondary outcomes

1

Description

Body fat percentage

Timepoint

First and 12 weeks later

Method of measurement

Caliper

2

Description

Waist-hip ratio (WHR)

Timepoint

First and 12 weeks later

Method of measurement

meters

3

Description

Body Mass Index

Timepoint

First and 12 weeks later

Method of measurement

Digital scales and meters

Intervention groups

1

Description

Intervention group: heavy interval training, Three times a week, 12 weeks, with an intensity of 88-93% of maximum heart rate, Duration of activity from the beginning to the end of the protocol (25 to 60 minutes)

Category

Other

2

Description

Intervention group: medium interval training, Three times a week, 12 weeks, with an intensity of 73-78% of maximum heart rate, Duration of activity from the beginning to the end of the protocol (25 to 60 minutes)

Category

Other

3

Description

En Intervention group: low interval training, Three times a week, 12 weeks, with an intensity of 58-63% of maximum heart rate, Duration of activity from the beginning to the end of the protocol (25 to 60 minutes)

Category

Other

4

Description

Control group: Lack of exercise within 12 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhangian university, Campus of imam mohammad bagher (AS) bojnourd

Full name of responsible person

Saeed ramezani

Street address

No. 39, Aaref 1, Chamran1 Ave., Chamran Ave

City

Bojnourd

Province

North Khorasan

Postal code

9418795569

Phone

+98 58 3232 3963

Email

rsaeid92@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Tehran

Full name of responsible person

Ali Asghar Ravasi

Street address

Enghelab Square

City

Tehran

Province

Tehran

Postal code

1417414418

Phone

+98 21 6111 8812

Email

publicrei@ut.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 Tehran

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

The University of Tehran

Full name of responsible person

Saeed Ramezani

Position

The Student of PHD

Latest degree

Master

Other areas of specialty/work

Biochemistry

Street address

No. 39, Aaref 1, Chamran1 Ave., Chamran Ave

City

Bojnourd

Province

North Khorasan

Postal code

9418795569

Phone

+98 58 3232 3963

Fax**Email**

rsaeid92@gmail.com

Position

Student of PHD

Latest degree

Master

Other areas of specialty/work

Biochemistry

Street address

No. 39, Aaref 1, Chamran1 Ave., Chamran Ave

City

Bojnourd

Province

North Khorasan

Postal code

9418795569

Phone

+98 58 3232 3963

Fax**Email**

rsaeid92@gmail.com

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

The University of Tehran

Full name of responsible person

Saeed Ramezani

Position

Student of PHD

Latest degree

Master

Other areas of specialty/work

Biochemistry

Street address

No. 39, Aaref 1, Chamran1 Ave., Chamran Ave

City

Bojnourd

Province

North Khorasan

Postal code

9418795569

Phone

+98 58 3232 3963

Fax**Email**

rsaeid92@gmail.com

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

The University of Tehran

Full name of responsible person

Saeed Ramezani

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

No abuse of raw data

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

All data is shared after being unidentified

When the data will become available and for how long

One year after the publication of the results

To whom data/document is available

All people who need this data

Under which criteria data/document could be used

Lake of Plagiarism

From where data/document is obtainable

Saeed Ramezani, rsaeid92@gmail.com

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

A week after sending a request to Gmail and an applicant's commitment to not use the data directly

Comments

The main concern of each researcher is the misuse of others by his research information. If this item is assured, all research information will be available.