

# 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

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**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.