

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Effects of combined resistance and aerobic training with Tirzepatide on some anthropometric factors, physical fitness, cardiovascular risk factors and insulin resistance in prediabetic obese soldiers

#### Protocol summary

##### Study aim

Investigating the effects of combined resistance and aerobic exercises with the consumption of different doses of Tirzepatide on some anthropometric factors, physical fitness, cardiovascular risk factors and insulin resistance in obese pre-diabetic soldiers will be the research objectives.

##### Design

The sample size will be obtained by G-power software. Participants will be studied for 6 weeks. The training groups will train 3 times a week and tirzepatid injection will be done once a week in the subcutaneous area of the abdomen by a physician.

##### Settings and conduct

The study will be done in Amol city and in Kolak sports club. Physical fitness factors will include cardio-respiratory fitness and muscle strength. Lipid profile including triglyceride (TG), total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C) will be measured. Insulin resistance will be determined using the Homeostasis Model of Insulin Resistance Assessment (HOMA-IR).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are: age range 18-30 years, fasting glucose level 100-125 mg/dL, BMI > 30 kg/m<sup>2</sup>, not participating in regular physical activity in the last six months, absence of cardiovascular, metabolic disease and endocrine glands and not using drugs and alcohol. The exclusion criteria for the study are: lack of regular attendance in training, inflammatory and severe diseases, possible injuries, personal problems.

##### Intervention groups

The participants were randomly divided into six groups of 13 people: 1. Placebo (distilled water), 2. Tirzepatide (2.5 mg), 3. Tirzepatide (5 mg), 4. Combined training + placebo, 5. Combined training + Tirzepatide (2.5 mg) and 6. combined training + Tirzepatide (5 mg) will be

divided.

##### Main outcome variables

Physical fitness, lipid profile and insulin resistance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230804059029N1**

Registration date: **2023-08-06, 1402/05/15**

Registration timing: **prospective**

Last update: **2023-08-06, 1402/05/15**

Update count: **0**

##### Registration date

2023-08-06, 1402/05/15

##### Registrant information

##### Name

Behnam Bagherzadeh Rahmani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 8243 0713

##### Email address

b.bagherzadehrahmani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-15, 1402/05/24

##### Expected recruitment end date

2023-09-27, 1402/07/05

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of combined resistance and aerobic training with Tirzepatide on some anthropometric factors, physical fitness, cardiovascular risk factors and insulin resistance in prediabetic obese soldiers

**Public title**

Effects of exercise training with Tirzepatide on obese soldiers

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age range from 18 to 30 years, fasting glucose level 100-125 mg/dL, BMI > 30 kg/m<sup>2</sup>, not participating in regular physical activity in the last six months, absence of cardiovascular, metabolic and endocrine diseases, and absence of consumption Drugs and alcohol

**Exclusion criteria:**

Lack of regular attendance in training, inflammatory and severe diseases, possible injuries, personal problems

**Age**

From **18 years** old to **30 years** old

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **58**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The participants were randomly divided into six groups of 13 people: 1. Placebo (distilled water), 2. Tirzepatide (2.5 mg), 3. Tirzepatide (5 mg), 4. Combined training + placebo, 5. Combined training + Tirzepatide ( 2.5 mg) and 6. combined training + Tirzepatide (5 mg) will be divided.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Hakim Sabzevari University

**Street address**

Islamic Republic Of Iran-Khorasan Razavi-Sabzevar-Hakim Sabzevari University

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617976487

**Approval date**

2023-07-23, 1402/05/01

**Ethics committee reference number**

IR.HSU.REC.1402.015

**Health conditions studied****1****Description of health condition studied**

Obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

**Primary outcomes****1****Description**

Muscular strength

**Timepoint**

Pre-test and post-test

**Method of measurement**

Indirectly using chest press and leg press

**2****Description**

Insulin resistance

**Timepoint**

Pre-test and post-test

**Method of measurement**

Insulin resistance will be determined using the homeostasis model of insulin resistance assessment (HOMA-IR), after measuring fasting blood glucose (FBG) and insulin.

**3****Description**

Lipid profile

**Timepoint**

Pre-test and post-test

**Method of measurement**

Lipid profile including triglyceride (TG), total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C) and

high-density lipoprotein cholesterol (HDL-C) will be measured.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: Participants in the control group will continue their normal lifestyle during the study and will receive the placebo once a week.

#### Category

Placebo

### 2

#### Description

Intervention group: Participants in the Tirzepatide 2.5 mg group will continue their usual lifestyle during the study and will receive Tirzepatide (2.5 mg) once a week.

#### Category

Prevention

### 3

#### Description

Intervention group: Participants in the Tirzepatide 5 mg group will continue their usual lifestyle during the study and will receive Tirzepatide (5 mg) once a week.

#### Category

Prevention

### 4

#### Description

Intervention group: Participants in the group of combined training + placebo will perform three sessions of combined training during the research and will receive the placebo once a week.

#### Category

Treatment - Other

### 5

#### Description

Intervention group: The participants in the group of combined training + Tirzepatide 2.5 mg will perform three sessions of combined training per week during the research and will receive Tirzepatide 2.5 mg once a week.

#### Category

Prevention

### 6

#### Description

Intervention group: The participants in the group of combined training + Tirzepatide 5 mg will perform three sessions of combined training per week during the

research and will receive Tirzepatide 5 mg once a week.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The center of the vice-research and technology of the army

##### Full name of responsible person

Esmail Karami

##### Street address

Joint Headquarters of the Republic of Iran Army -  
Tehran - District 7 - Shariati - Qudousi Crossroads

##### City

Tehran

##### Province

Tehran

##### Postal code

16316

##### Phone

+98 21 8841 5061

##### Email

esi.karami67@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Seyed Hossein Mousavi

##### Street address

Tehran, District 6, Fatemi Neighborhood, Army  
University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

##### Phone

+98 21 8802 8350

##### Email

dr.shmusavi@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Artesh University of Medical Sciences

#### 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**  
Hakim Sabzevari University  
**Full name of responsible person**  
Behnam Bagherzadeh-Rahmani  
**Position**  
Lecturer  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiology  
**Street address**  
40 Darya Alley, No. 19  
**City**  
آمل  
**Province**  
Mazandaran  
**Postal code**  
4615886731  
**Phone**  
+98 11 4308 2713  
**Email**  
b.bagherzadehrahmani@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hakim Sabzevari University  
**Full name of responsible person**  
Behnam Bagherzadeh-Rahmani  
**Position**  
Lecturer  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiology  
**Street address**  
40 Darya Alley, No. 19  
**City**  
آمل  
**Province**  
Mazandaran  
**Postal code**

4615886731

**Phone**  
+98 11 4308 2713

**Email**  
b.bagherzadehrahmani@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hakim Sabzevari University  
**Full name of responsible person**  
Behnam Bagherzadeh-Rahmani  
**Position**  
Lecturer  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiology  
**Street address**  
40 Darya Alley, No. 19  
**City**  
آمل  
**Province**  
Mazandaran  
**Postal code**  
4615886731  
**Phone**  
+98 11 4308 2713  
**Email**  
b.bagherzadehrahmani@gmail.com

## 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

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

### Analytic Code

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

### Data Dictionary

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