Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 tirspatid 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/m2, 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/m2, 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
۹۶۱۷۹۷۶۴۸۷
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

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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

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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