

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of a 12-week combined exercise training program on lipid peroxidation, total antioxidant capacity, high-sensitivity C-reactive protein, body composition, physical function, and lipid profile in women with subclinical hypothyroidism

Protocol summary

Study aim

Investigating the effect of combined exercises on lipid peroxidation, total antioxidant capacity, high-sensitivity C-reactive protein, body composition, physical performance, and lipid profile.

Design

The clinical trial has a control group and an exercise group, each group has a sample of 22 people. After completing all the initial evaluations, the subjects will be divided into the training group and the control group using two block randomization in order to balance the number of samples allocated. Also, due to the importance of concealing the random allocation, a sealed envelope is used. It is intended to perform random blocking based on age and one of the body composition indicators such as body mass index or fat percentage.

Settings and conduct

- Location of the project: Isfahan city - Intervention: combined exercise training (resistance and aerobic exercises)

Participants/Inclusion and exclusion criteria

- TSH between 5 and 10 mu/l
- No special disease and no medication
- Same body mass index
- No pregnant
- No regular exercise training for at least six months
- No smoking
- No alcohol consumption
- Not using food supplements containing zinc, magnesium and vitamin A during the last 3 months

Intervention groups

The control group does not receive any exercise The intervention group receives two types of resistance training with elastic bands and aerobic training. which is resistance training with 60 to 75% of a maximum repetition in the range of 12 to 14 repetitions and aerobic exercise with an intensity of 40 to 60% of Vo2max is performed on a bicycle or treadmill ergometer

Main outcome variables

Malondialdehyde High-sensitivity C-reactive protein TC TG LDL-C HDL-C Total antioxidant capacity Body fat percentage Waist to hip ratio (WHR) Body mass index (BMI) "The result of the 30-second test of getting up from the chair" "The result of the 30-second arm curl test"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220809055643N1**

Registration date: **2022-08-16, 1401/05/25**

Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**

Update count: **0**

Registration date

2022-08-16, 1401/05/25

Registrant information

Name

Javad Najafi

Name of organization / entity

The university of Shahrekord

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15
Expected recruitment end date
 2022-10-07, 1401/07/15
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Effect of a 12-week combined exercise training program on lipid peroxidation, total antioxidant capacity, high-sensitivity C-reactive protein, body composition, physical function, and lipid profile in women with subclinical hypothyroidism

Public title
 Effect of combined exercise training on subclinical hypothyroidism variables

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 TSH between 5 and 10 mu/l No special disease and no medication Same body mass index No pregnant no regular exercise training for at least six months before participating in this study No smoking No alcohol consumption Not using food supplements containing zinc, magnesium and vitamin A during the last 3 months
Exclusion criteria:
 Diagnosis of the attending physician regarding the need to withdraw from the study Personal desire to withdraw from the study Getting other diseases

Age
 From **35 years** old to **49 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **54**

Randomization (investigator's opinion)
 Randomized

Randomization description
 After completing all the initial evaluations, the subjects will be divided into the training group and the control group using two block randomization in order to balance the number of samples allocated. Also, due to the importance of concealing the random allocation, a sealed envelope is used. It is intended to perform random blocking based on age and one of the body composition indicators such as body mass index or fat percentage.

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

A new and safe training system, as well as exploring variables that have been less explored.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee in Shahrekord University

Street address

Shahrekord University, Blvd Rahbar, Shahrekord

City

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Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818634141

Approval date

2022-07-26, 1401/05/04

Ethics committee reference number

IR.SKU.REC.1401.26

Health conditions studied

1

Description of health condition studied

Subclinical hypothyroidism

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lipid peroxidation

Timepoint

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

Method of measurement

Measurement of malondialdehyde through blood sample taken by valid laboratory kits

2

Description

Total antioxidant capacity

Timepoint

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

Method of measurement

Measurement of antioxidant capacity through blood samples taken by valid laboratory kits

3

Description

C-reactive protein with high sensitivity

Timepoint

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

Method of measurement

Measurement of C-reactive protein level in blood sample by valid laboratory kits

4

Description

Blood lipid profile

Timepoint

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

Method of measurement

Measuring the level of lipid profile in the blood sample by valid laboratory kits

5

Description

Body fat percentage

Timepoint

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

Method of measurement

Measurement of the thickness of subcutaneous fat (triceps brachialis, Supraspinatus and thigh) using calipers and formula calculations.

6

Description

Waist to hip ratio

Timepoint

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

Method of measurement

Measure waist circumference at the narrowest point divided by hip circumference at the widest point

7

Description

Body mass index

Timepoint

24 hours before the beginning of the interventions - 48 hours after the end of the interventions

Method of measurement

Measure weight in kilograms by height in meters to the power of two

Secondary outcomes

1

Description

Lipid peroxidation

Timepoint

48 hours after the last training session

Method of measurement

Malondialdehyde measurement through a blood sample taken by a valid laboratory kit

2

Description

Total antioxidant capacity

Timepoint

48 hours after the last training session

Method of measurement

Measuring the antioxidant capacity of blood by valid laboratory kits

3

Description

C-reactive protein with high sensitivity

Timepoint

48 hours after the last training session

Method of measurement

Measurement of C-reactive protein level in blood by valid laboratory kits

4

Description

Lipid profile

Timepoint

48 hours after the last training session

Method of measurement

Measurement of lipid profile components in blood by valid laboratory kits

5

Description

Body fat percentage

Timepoint

48 hours after the last training session

Method of measurement

Measurement of the thickness of subcutaneous fat (triceps brachialis, Supraspinatus and thigh) using calipers and formula calculations.

6

Description

Waist to hip ratio

Timepoint

48 hours after the last training session

Method of measurement

Waist circumference at the lowest point divided by hip circumference at the widest part

7

Description

Body mass index

Timepoint

48 hours after the last training session

Method of measurement

Weight in kilograms divided by height in meters to the power of two

Intervention groups

1

Description

Intervention group: receiving a resistance exercise program with an elastic band and performing an aerobic program on a treadmill or an exercise bike.

Category

N/A

2

Description

Intervention group: Subjects in the intervention group receive two types of exercises for 12 weeks. At the beginning of each session, 10 minutes of warm-up exercises, then 5 minutes of stretching exercises - after that, 20 minutes of resistance exercises using an elastic band with an intensity of 60 to 75%, a maximum repetition in the range of 12 to 14 repetitions, and then aerobic exercises on a ergometer or Treadmill will be done with 40 to 60% Vo2max for 30 minutes, and at the end stretching movements will be done to cool down the body.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrine and Metabolism Research Center

Full name of responsible person

Mr. Dr. Sasan Haghighi

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

No

Title of funding source

Payment of financial resources by the researcher

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University

Full name of responsible person

Javad Najafi

Position

Masters student

Latest degree

Master

Other areas of specialty/work

Exercise physiology

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After the relevant article is printed

When the data will become available and for how long

Access starts 3 months after results are published

To whom data/document is available

Everyone and public

Under which criteria data/document could be used

Prevention and treatment

From where data/document is obtainable

Internet

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

search

Comments