

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

**The effect of combined exercise on plasma levels of alpha-klotho, sirtuin 1, oxidative enzymes, lipid profile and glucose homeostasis in obese men aged 60 to 70 years.**

### Protocol summary

#### Study aim

The effect of combined training on alpha-KLOTHO, sirtuin 1, oxidative enzymes, glucose homeostasis and lipid profile in obese men aged 60 to 70 years.

#### Design

The type of this research is semi-experimental and in this research, the statistical population includes inactive obese elderly men. To determine the size of the sample using G-POWER software, it was equal to 46 and was divided into two groups of 23 people including the experimental group and the control group.

#### Settings and conduct

The 16-week exercises will be combined endurance and resistance exercises in 3 sessions for 60 minutes. Under the supervision of a trainer and doctor

#### Participants/Inclusion and exclusion criteria

Entry criteria: Subjects between 60 and 70 years old; people who have the ability to implement the training protocol and tests; stable body weight, and the ability to perform sports intervention. Exclusion criteria: history of orthopedic diseases in the last 5 years and vision problems; having daily sports activities for at least two years; having suspected cases such as cardiovascular disease; having kidney failure and liver disease; coagulation disorders, chronic digestive disorders, pancreatic insufficiency, immunological disease and type 1 and 2 diabetes.

#### Intervention groups

The intervention group of 60 to 70-year-old men who are able to perform resistance and endurance exercises in this research. The control group of 60 to 70-year-old men go about their daily routine in these 16 weeks

#### Main outcome variables

SαKI SIRT1, FOXO, oxidative enzymes as well as glucose homeostasis and lipid levels of physical fitness, body composition and blood pressure and heart rate in obese elderly

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230810059112N1**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **retrospective**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

#### Registration date

2023-09-18, 1402/06/27

#### Registrant information

##### Name

Maryam Safari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 4234 4958

##### Email address

ma.aq8313@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-04-14, 1401/01/25

#### Expected recruitment end date

2022-06-15, 1401/03/25

#### Actual recruitment start date

2022-04-14, 1401/01/25

#### Actual recruitment end date

2022-06-15, 1401/03/25

#### Trial completion date

2022-10-22, 1401/07/30

## Scientific title

The effect of combined exercise on plasma levels of alpha-klotho, sirtuin 1, oxidative enzymes, lipid profile and glucose homeostasis in obese men aged 60 to 70 years.

## Public title

The effect of combined exercise on plasma levels of alpha-glucose, sirtuin 1, oxidative enzymes, lipid profile and glucose homeostasis in obese men aged 60 to 70 years.

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

The subjects were between 60 and 70 years old People who have the ability to implement the training protocol and tests Stable body weight ( $\pm 5$  kg) for at least six months Ability to perform the exercise intervention (exercise capacity) and participants consuming an omnivorous diet

### Exclusion criteria:

History of orthopedic diseases in the last 5 years and vision problems Having daily sports activities for at least two years Having suspicious cases such as cardiovascular disease, angina pectoris, myocardial infarction, stroke, peripheral artery occlusion disease Having kidney failure and liver disease, coagulation disorders, chronic gastrointestinal disorders (e.g. Crohn's disease), pancreatic insufficiency, immunological disease (e.g. autoimmune disease) and not taking immunosuppressive drugs or laxatives, heart failure, cardiac arrhythmia, type 1 and 2 diabetes

## Age

From **60 years** old to **70 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **46**

Actual sample size reached: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random assignment to intervention and control groups The simple random method of the lottery method, each name removed was placed in one of the two study groups

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Islamic Azad University-Rasht Branch (Research Ethics Committee)

##### Street address

Lakani Street - Azad University, Rasht Branch

##### City

Rasht

##### Province

Guilan

##### Postal code

4147654919

#### Approval date

2022-07-20, 1401/04/29

#### Ethics committee reference number

IR.IAU.RASHT.REC.1401.010

## Health conditions studied

### 1

#### Description of health condition studied

The study subjects are obese

#### ICD-10 code

E66

#### ICD-10 code description

Overweight and obesity

## Primary outcomes

### 1

#### Description

levels of klotho

#### Timepoint

Before and after the end of 16 weeks of training

#### Method of measurement

ELISA method

### 2

#### Description

Sirtuin1

#### Timepoint

Before and after the end of 16 weeks of training

#### Method of measurement

ELISA method

### 3

#### Description

Catalase enzyme

#### Timepoint

Before and after the end of 16 weeks of training

**Method of measurement**

ELISA method

**4****Description**

Superoxide dismutase enzyme

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

ELISA method

**5****Description**

Total antioxidant capacity

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

ELISA method

**6****Description**

FOXO1

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

ELISA method

**7****Description**

Insulin-like growth factor-1 (IGF-1)

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

ELISA method

**8****Description**

Insulin

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

ELISA method

**9****Description**

Fasting blood sugar

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

By photometric enzymic calorimetric

**10****Description**

Triglyceride

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

Enzymatic calorimetric method

**11****Description**

High density lipoprotein

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

Enzymatic calorimetric method

**12****Description**

Low density lipoprotein

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**Through the equation of Friedwald et al( $LDL = TC - HDL - TG/0.5$ )**13****Description**

Total cholesterol

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

Enzymatic photometric method

**14****Description**

Ability and capacity to perform basic movements and mobility

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

TUG standing and walking time test

**15****Description**

Aerobic strength

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

Using Racport

**16****Description**

Hand and paw strength test(hand grip)

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

Hand and paw strength test(hand grip)with a dynamometer

**17****Description**

Lower body muscle strength

**Timepoint**

Before and after the end of 16 weeks of training

**Method of measurement**

30 second sitting on a chair test

**Secondary outcomes**

**1**

**Description**

Blood pressure and heart rate

**Timepoint**

Before and after 16 weeks of training

**Method of measurement**

Variables were measured at rest and after exercise with a sphygmomanometer, systolic and diastolic blood pressure and heart rate

**2**

**Description**

Body composition

**Timepoint**

Before and after 16 weeks of training

**Method of measurement**

Using weight, body mass index, waist to hip ratio and fat percentage

**Intervention groups**

**1**

**Description**

In this study, the intervention is sports training, which will be combined training (resistance, endurance) for 16 weeks and 3 sessions per week for 60 minutes. Before the start of the training period, in order to know about the health status and level of preparation of the people, the PARQ physical activity readiness questionnaire will be used. Before starting the main exercises, the subjects are taught exercises for a week. The combined training group has a 16-week training program that consists of three sessions each week and each session lasts 60 minutes. Aerobic and resistance exercises will be held in the morning (6:30 to 7:30). First stage, general warm-up for 10 minutes (walking, soft running, stretching and mobility), performing aerobic exercises for 45 to 60 minutes with an intensity equal to 50 to 70 percent of the reserve heart rate and a training session that gradually starts from 30 minutes and increases to 60 minutes at the end of the course (Hijazi, 2017). Weight training can be harmful for inexperienced seniors unless it is done under the supervision of a trainer. Therefore, doing resistance exercises with body weight can be more safe and attractive for the elderly, that's why resistance exercises for 10 to 15 minutes with weight bearing to strengthen the muscles of the lower and middle limbs with movements such as squats, lunges, long and Sit-ups, planks and lateral planks (both sides of the body), triceps dip will take place in Lahijan Park (Lahijan Pool). which starts with 2 sets of 10 repetitions in the first weeks and increases to 3 sets of 15 repetitions in the 16th week. At the end of each

training session, the body returns to its initial state and cools down for 10 minutes (slow running, walking and stretching exercises). will be done. These exercises will last up to 16 weeks. Anthropometric tests will be done 48 hours before and laboratory tests before the first training session, and after 16 weeks of training, tests and blood tests will be repeated for both groups. It should also be mentioned that at the beginning and after 16 weeks of training, laboratory tests including SαKI, SIRT1, CAT, ROS, SOD, IGF-1, HDL, LDL, cholesterol and triglycerides, FBS, insulin and HOMA-IR blood serum, capacity It is a plasma antioxidant. It should be noted that blood samples are collected 24 hours before training and 24 hours after training for both groups. Sampling will be done between 8 and 10 am in the laboratory, from the vein of the left hand of each subject, while sitting and resting (Hijazi, 2017). Blood samples will be poured into test tubes containing anticoagulant. Then it is centrifuged at 3000 rpm for 10 minutes and the separated plasma is used for analysis. Also, field tests including stand-up and walking time test, Rockport test, consecutive jumps for anaerobic power, hand and paw strength test for upper limb strength, lower limb muscle strength from "sitting on a chair for 30 seconds" test will be used.ention group:

**Category**

Lifestyle

**2**

**Description**

Control group: This group performed field and laboratory tests at the beginning and after 16 weeks, and no intervention was performed.

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Aria Clinic

**Full name of responsible person**

Maryam Safari Sharafshadeh

**Street address**

Kashif Street, Aria Clinic

**City**

Lahijan

**Province**

Guilan

**Postal code**

4419646735

**Phone**

+98 13 4234 4958

**Email**

ma6692.safari@gmail.com

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali delpasand

**Street address**

Lacan Gate, Rasht Azad University, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 3342 4080

**Email**

shabani\_msn@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Maryam Safari Sharafshadeh

**Position**

Student of Azad University, Rasht branch

**Latest degree**

Master

**Other areas of specialty/work**

Others

**Street address**

Lacan Gate, Rasht Azad University, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 3342 4080

**Email**

ma6692.safari@gmail.com

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ramin Shabani

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

فیزیولوژی ورزشی

**Street address**

Lacan Gate, Rasht Azad University, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 3342 4080

**Email**

shabani\_msn@yahoo.com

### Person responsible for updating data

**Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Maryam Safari Sharafshadeh

**Position**

PhD student of Islamic Azad University, Rasht branch

**Latest degree**

Master

**Other areas of specialty/work**

Exercise physiology

**Street address**

Lacan Gate, Rasht Azad University, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 4234 4958

**Email**

ma6692.safari@gmail.com

### 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**

In the study of the effect of combined training on the plasma levels of alpha klotho, 1, oxidative enzymes, lipid profile and glucose homeostasis in obese men 60 to 70 years after being unidentifiable, part of the data and the outcome of the type of training can be shared.

**When the data will become available and for how long**

Beginning of access in the first half of 2024 until 6 months after the publication of the article.

**To whom data/document is available**

Researchers working in academic and scientific institutions are available.

**Under which criteria data/document could be used**

The use of data should be within the framework of the laws and should not be misused.

**From where data/document is obtainable**

To the researcher - Islamic Azad University, Rasht branch

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

Send a message to the researcher's email. Responds as soon as possible.

**Comments**