

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Endurance Training along with cur Cumin Supplementation on the levels of Lipocalin-2 and Lipid profile in Sedentary Women.

#### Protocol summary

##### Study aim

Explaining the Effect of 12 weeks of Endurance training with Cur cumin Supplementation on Lipocalin\_2 levels and lipid profile in Inactive Women.

##### Design

First in several public places, parks, streets, offices and. The city of Tehran was informed and through the distribution of leaflets and tracts, eligible people were called 44 people were randomly selected to participate in the Researcher Intervention.

##### Settings and conduct

Subjects were present in the pre-test stage to measure the variables and blood samples were taken in the pre-test stage. Also, their height and weight will be measured with scales and gauges Placebo Take the placebo and continue the normal daily life of 11 people Cur cumin supplementation Cur cumin Supplementation and Non-Aerobic Exercise 11 people Aerobic Exercise taking placebo and 12 weeks Aerobic exercise 11 people.

##### Participants/Inclusion and exclusion criteria

Overweight Women between the ages of 27 and 40 Lack of diseases such as type 2 diabetes, Hypertension and so on At least in recent years, Subjects have not participated in a regular Exercise Program.

##### Intervention groups

Cur cumin Supplementation on Lipocalin\_2 levels and Lipid profile in Inactive Women in four equal groups including Placebo and Cur cumin Supplementation and aerobic Exercise and training Aerobic + Cur cumin Supplements were divided.

##### Main outcome variables

Community Health. Prevention of Cardiovascular disease. Type 2 diabetes.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220305054187N1**

Registration date: **2022-05-12, 1401/02/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-12, 1401/02/22**

Update count: **0**

##### Registration date

2022-05-12, 1401/02/22

##### Registrant information

###### Name

Saeed Rezaee

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2308 2902

###### Email address

saeedrezaeesport@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-20, 1401/01/31

##### Expected recruitment end date

2022-06-21, 1401/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Endurance Training along with cur Cumin Supplementation on the levels of Lipocalin-2 and Lipid profile in Sedentary Women.

##### Public title

Investigation of CurCumin on Lipocalin-2 levels and Lipid profile in Inactive Women.

**Purpose**

Health service research

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

Inclusion criteria are Non-Participation of Subjects in regular Exercise during the past year. No infection to Type 2 diabetes No infection to other chronic diseases such as cancer, Have not history of heart disease. No physical limitations and Medical To Participate in Sports Exercises.

**Exclusion criteria:****Age**

From **27 years** old to **40 years** old

**Gender**

Female

**Phase**

1-2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For Randomization, we divide the Subjects into four groups: Placebo group from number 1 to 11 cur cumin Supplement group from number 12 to 22 Aerobic exercise group from number 23 to 33 and Aerobic Exercise Group and cur cumin Supplement from Number 34 to 44 that each person must select a number from the container that has been prepared for this case and Numbers 1 to 44 are already in it.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Supplements and Placebo are in the hands of a third party. The Researcher and the Subject did not know about the pills taken so that the Researcher did not have a bias towards the Exercise Group.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee Headquarters of the Ministry of Health.

**Street address**

North Seol, vanak, tehran, Ministry of Sport and Youth

**City**

Tehran

**Province**

Tehran

**Postal code**

1995613711

**Approval date**

2022-02-26, 1400/12/07

**Ethics committee reference number**

IR.IAU.SRB.REC.1400.297

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

The Effect of Endurance training with Cur cumin Supplementation on Lipocalin\_2 levels and lipid profile In inactive women.

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The blood samples are immediately poured into a Falcon tube and then centrifuged at 3,000 rpm for 15 minutes to separate the serum. Serum samples were also stored in the freezer until blood variables were measured.

Measurements of lipocalin\_2 and cholesterol, triglyceride levels are performed using Pars Company kit.

**Timepoint**

Blood sampling training week at the beginning and end of 12 weeks.

**Method of measurement**

Blood sampling

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Curcumin Supplement Group.

**Category**

Lifestyle

**2****Description**

Aerobic Exercise Group.

**Category**

Lifestyle

### 3

#### Description

Intervention Group: Aerobic Exercise and cur Cumin Supplement.

#### Category

Lifestyle

### 4

#### Description

Control Group: Pharmacologica Group.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Parks and Streets of Tehran.

##### Full name of responsible person

SAEED REZAAE

##### Street address

North Seol, Vanak, Tehran, Ministry of Sport and Youth

##### City

TEHRAN

##### Province

Tehran

##### Postal code

1995613711

##### Phone

+98 21 2308 2902

##### Fax

+98 21 2308 2907

##### Email

saeedrezaeesport@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

SAEED REZAAE

##### Street address

Hesarak Martyrs Boulevard, University Square,

##### City

TEHRAN

##### Province

Tehran

##### Postal code

1477893855

##### Phone

+98 21 4486 5154

##### Email

saeedrezaeesport@gmail.com

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

SAEED REZAAE

#### 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

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Saeed Rezaee

##### Position

Employee of Ministry of Sport an Youth

##### Latest degree

Master

##### Other areas of specialty/work

Anatomy

##### Street address

North Seol, Vanak, Tehran, Minietry of Sport and Youth.

##### City

TEHRAN

##### Province

Tehran

##### Postal code

1995613711

##### Phone

+98 21 2308 2902

##### Email

saeedrezaeesport@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

SAEED REZAAE

##### Position

Employee of Ministry of Sport and Youth

##### Latest degree

Bachelor

##### Other areas of specialty/work

Health Promotion

##### Street address

North Seol, Vanak, Tehran,

##### City

TEHRAN  
**Province**  
Tehran  
**Postal code**  
1995613711  
**Phone**  
009826082902  
**Email**  
saeedrezaeesport@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
SAEED REZAAEE  
**Position**  
Employee of Ministry Sport and Youth  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Health Promotion  
**Street address**  
North Seol, Vanak, Tehran.  
**City**  
TEHRAN  
**Province**  
Tehran  
**Postal code**  
19995613711  
**Phone**  
+98 21 2308 2902  
**Email**  
saeedrezaeesport@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

No - There is not a plan to make this available

### Informed Consent Form

No - There is not 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

Explain the Effect of 12 weeks of endurance training with Curcumin Supplementation on lipocalin\_2 levels and lipid profile Inactive in women. Information about the main outcome can be shared.

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

6 Month later after publishing result

### To whom data/document is available

Every one

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

For study

### From where data/document is obtainable

SAEED REZAAEE

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

Through by email

### Comments