

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

**The effect of eight weeks of resistance training and consumption of garlic Extract on some biomarkers of oxidative stress, malondialdehyde (MDA) and reduced glutathione (GSH) in women with hyperlipidemia and type 2 diabetes.**

### Protocol summary

#### Study aim

Determining the effect of eight weeks of resistance training and consumption of garlic extract on some biomarkers of oxidative stress, malondialdehyde (MDA) and reduced glutathione (GSH) in women with hyperlipidemia and type 2 diabetes.

#### Design

Clinical trial with control group, with parallel groups, randomized, on 60 patients. Randomization by the method of equal blocks (15 blocks of 4) in which a number of intervention people and a number of comparison people are included in each block.

#### Settings and conduct

By referring to Hamedan Ba'ath Hospital, eligible people were identified and placed in the intervention groups using equal blocks randomization (15 blocks of 4). Then, people will go to the sports club for training intervention and perform exercises and supplements for 8 weeks. And before and 24 hours after exercise interventions, blood samples are taken from people to be measured in the laboratory.

#### Participants/Inclusion and exclusion criteria

Entry conditions: having diabetes and high blood lipids  
Conditions of non-entry: inability to practice

#### Intervention groups

Exercise and supplement group: In the exercise group, the samples are subjected to resistance training, and the supplement group consumes garlic extract. The control group is not subjected to any intervention.

#### Main outcome variables

Diabetes, some biomarkers of oxidative stress malondialdehyde (MDA) and reduced glutathione (GSH)

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20221120056548N8**

Registration date: **2023-07-09, 1402/04/18**

Registration timing: **prospective**

Last update: **2023-07-09, 1402/04/18**

Update count: **0**

#### Registration date

2023-07-09, 1402/04/18

#### Registrant information

##### Name

Saeid Shamlou kazemi

##### Name of organization / entity

Bu-Ali Sina university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 859 7297

##### Email address

saeidshamlou9092@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-07-12, 1402/04/21

#### Expected recruitment end date

2023-07-22, 1402/04/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

## Scientific title

The effect of eight weeks of resistance training and consumption of garlic Extract on some biomarkers of oxidative stress, malondialdehyde (MDA) and reduced glutathione (GSH) in women with hyperlipidemia and type 2 diabetes.

## Public title

Effect of exercise and consumption of garlic extract on diabetes

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having diabetes high blood fat being menopausal

### Exclusion criteria:

History of cardiovascular disease

## Age

From **50 years** old to **65 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this randomization, the method of equal blocks (15 blocks of 4) has been used, in which a number of intervention people and a number of comparison people are included in each block, and we have allocated them to different groups. The method and tool of block random sequence generation has been done using <https://www.sealedenvelope.com/simple-randomiser/v1/lits>.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Sport Sciences Research Institute

##### Street address

Fifth Alley, Mir Emad Ave., Ostad Motahari Ave

##### City

Tehran

## Province

Tehran

## Postal code

1474674646

## Approval date

2023-06-21, 1402/03/31

## Ethics committee reference number

IR.SSRC.REC.1402.064

## Health conditions studied

### 1

#### Description of health condition studied

diabetes

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

The percentage of people whose blood sugar levels have decreased.

#### Timepoint

Blood sugar measurement before and after the intervention

#### Method of measurement

By measuring blood sugar in the laboratory

### 2

#### Description

The percentage of people whose blood fat level has decreased.

#### Timepoint

Measurement of blood lipids before and after the intervention

#### Method of measurement

By measuring blood lipids in the laboratory

## Secondary outcomes

### 1

#### Description

The percentage of people in whom the level of antioxidant glutathione increased and malondialdehyde decreased.

#### Timepoint

Before and after interventions

#### Method of measurement

Using ELISA method and Zelbio kit made in Germany

## Intervention groups

## 1

### Description

Intervention group: Sports intervention includes 8 weeks of combined exercises (selected aerobic and resistance exercises). According to the instructions of the American College of Sports Medicine (ACSM), the participants start training three times a week for fifty minutes, and the intensity and duration of the training is increased during 8 weeks. All exercises are performed under the supervision of a sports physiology specialist and in the health sports clinic. During eight weeks of resistance training, in each training session, the subjects performed three lower body movements (leg press, front thigh press, and back thigh press) and six upper body movements (chest press, cable underarm, lateral push, cable back arm, front arm, and crunch). base) will be performed by starting the lower body movements and then the upper body with an intensity of 80% of a maximum repetition. These exercises will include three sets of 10 repetitions for both upper and lower body parts with 1 minute rest between sets and movements. The supplement group will be given a daily garlic capsule - each containing 500 mg of garlic extract supplement (produced by Goldaro, Iran) - for 8 weeks, and the third group will exercise and take the supplement at the same time.

### Category

Treatment - Other

## 2

### Description

Control group: This group is not subjected to any exercise intervention and supplement consumption.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Besat Hospital

#### Full name of responsible person

Saeid Shamlou Kazemi

#### Street address

Shahid Beheshti Blvd

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3264 0020

#### Email

saeidshamlou9092@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice President of Research at Danesh Alborz University

#### Full name of responsible person

Saeid Shamlou Kazemi

#### Street address

Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3221 0929

#### Email

saeidshamlou9092@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Vice President of Research at Danesh Alborz University

### Proportion provided by this source

10

### 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

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Bu-Ali Sina University

#### Full name of responsible person

Saeid Shamlou Kazemi

#### Position

Student

#### Latest degree

Master

#### Other areas of specialty/work

Sport Medicine

#### Street address

Mahdiyeh Ave

#### City

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#### Province

Hamadan

#### Postal code

6517838695

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Bu-Ali Sina University

**Full name of responsible person**

Saeid Shamlou Kazemi

**Position**

Student

**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**

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**

Yes - There is 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals

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

The access period starts 6 months after the results are published

**To whom data/document is available**

It will be available for researchers working in academic and scientific institutions.

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

If the intellectual rights are preserved, the data can be sent to the researchers.

**From where data/document is obtainable**

Email address: saeidshamlou9092@gmail.com

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

Submission of a written request (one week)

**Comments**