

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Study of the effect of eight week resistance training with ginger supplementation on oxidative stress and antioxidant index in type 2 diabetes

#### Protocol summary

##### Study aim

Effect of eight weeks resistance training and ginger supplementation on oxidative stress indices in type 2 diabetic patients

##### Design

Clinical trial, The group (placebo, ginger supplement, supplemented exercise, placebo training), community-based (type 2 diabetes association in Shiraz), and pragmatic, with parallel groups, blinded (then from a person who did not know the codes, It was asked to randomly list numbers from 1 to 44. The first 11 subjects in the placebo group, 11 in the supplement group, 11 in the training with supplement group, and the last 11 in the training with placebo group were placed.

Randomized;

##### Settings and conduct

Sport protocol for 8 weeks under the supervision of researcher and co-workers in Shiraz University and in Shiraz. Physical Fitness and Fitness Hall Resistive training was carried out both on-the-spot and on-line. None of the participants in the project, such as students, supervisor professors, consultant professors, and laboratory personnel, did not know how to educate the intervention of different groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Arthralgia and bone softness, bone fractures, smokers, and alcoholics, if used antioxidant supplements (including ginger, vitamin C, vitamin E), history of resistance exercise in one year Exclusion criteria: Sudden Diseases; Digestive Problems Caused by Supplements and Physical Problems

##### Intervention groups

Subjects were divided into four groups: ginger (8 subjects), placebo (8), resistance training with placebo (8), and resistance training with ginger (8)

##### Main outcome variables

In general, the purpose of this exercise was to evaluate

oxidative stress index and antioxidant index in patients with type 2 diabetes mellitus in Shiraz.

#### General information

##### Reason for update

##### Acronym

دیابت نوع دو

##### IRCT registration information

IRCT registration number: **IRCT20181205041856N1**

Registration date: **2019-02-09, 1397/11/20**

Registration timing: **retrospective**

Last update: **2019-02-09, 1397/11/20**

Update count: **0**

##### Registration date

2019-02-09, 1397/11/20

##### Registrant information

##### Name

Hamzeh Mohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4068

##### Email address

hamzeh.gh88@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-05-03, 1395/02/14

##### Expected recruitment end date

2016-07-04, 1395/04/14

##### Actual recruitment start date

2016-04-02, 1395/01/14

**Actual recruitment end date**

2016-05-02, 1395/02/13

**Trial completion date**

2016-09-20, 1395/06/30

**Scientific title**

Study of the effect of eight week resistance training with ginger supplementation on oxidative stress and antioxidant index in type 2 diabetes

**Public title**

The effect of resistance training and ginger supplementation on the index of superoxide dismutase, malondialdehyde and body composition of type 2 diabetes mellitus.

**Purpose**

Other

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

People between the ages of 40 and 60 year t least 3 years have passed Male gender Member of Diabetes Association of Shiraz Diagnosis of Type 2 diabetes by a specialist Informed consent It has a body composition of 25-29.9 kg / m 2

**Exclusion criteria:**

Not a professional athlete Not taking antioxidant supplements, selenium, zinc, beta-carotene, omega-3 ... At least 3 months before the start of the study. Not participating in another research project Absence of respiratory, metabolic, cardiovascular diseases Do not change the oral drug lowering blood glucose No Diabetic Complications No smoking and alcohol Disease associated with softness and bone

**Age**From **40 years** old to **60 years** old**Gender**

Male

**Phase**

1

**Groups that have been masked**

- Participant

**Sample size**Target sample size: **44**Actual sample size reached: **44**

More than 1 sample in each individual

Actual sample size in each individual: **11**

11

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, each of the subjects was coded by one person who was not involved in the research (classmates). Then, from someone who did not know the codes, they were asked to randomly list numbers from 1 to 44. The first 11 first placebo groups, 11 in the supplementation group, 11 in the supplementation and exercise groupe. The last 11 people were placed in the exercise with placebo group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All participants in the study (subjects) were aware of the need to consider the use of ginger supplements in this study, but were not aware of the contents of the capsules (placebo or ginger) that they consumed. The main investigators (student, supervisor, and counselor) have not been aware of which capsule (placebo or ginger) have been consumed before the end of the research. The laboratory personnel who have been responsible for sampling and measuring variables have not been informed about which subject the capsule (placebo or ginger) has consumed.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

Resistance training will be performed in a stationary and circular manner. The movements include leg press, chest press, pull-down triceps, knee extension, row seated, forward arm. It has biceps curl and abdominal crunch

**Secondary Ids**

empty

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

The Ethics Committee of Shiraz University of Medical Sciences

**Street address**

Shiraz, Zand Avenue, opposite the Palestine Street, Central Building of Shiraz University of Medical Sciences

**City**

shiraz

**Province**

Fars

**Postal code**

۱۴۳۳۶ - ۷۱۳۴۸

**Approval date**

2016-01-25, 1394/11/05

**Ethics committee reference number**

این پژوهش توسط کمیته اخلاق دانشگاه علوم پزشکی شیراز با کد های بالینی 9/38515/04/9/پ/94/ص تصویب شده و در پایگاه کارآزمایی ثبت شده است IR.SUMS.REC.1394.178 ایران با شماره

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

Type 2 diabetic patients

**ICD-10 code**

E11

**ICD-10 code description**

Type 2 diabetes mellitus

## Primary outcomes

### 1

#### Description

Malondialdehyde

#### Timepoint

Two months (from May 15, 2016 to July 15, 2016)

#### Method of measurement

The concentrations Malondialdehyde by spectrophotometer method

### 2

#### Description

superoxidedismutase

#### Timepoint

month two (from May 15, 2016 to July 15, 2016)

#### Method of measurement

Serum suproxid dismutase was calculated by ELISA reader.

## Secondary outcomes

### 1

#### Description

body composition

#### Timepoint

month two (Two months (from May 15 to July 15, 2016))

#### Method of measurement

body composition using a caliper device was calculated

### 2

#### Description

SOD

#### Timepoint

Two months from May 15, 2016 to July 15, 2016

#### Method of measurement

The concentration of superoxide dismutase index was calculated by ELISA method

### 3

#### Description

MDA

#### Timepoint

Two months from May 15, 2016 to July 15, 2016

#### Method of measurement

Concentration of MDA by spectrophotometer and Thiobarbituric Acid Test

## Intervention groups

### 1

#### Description

Control group: placebo Group

#### Category

Placebo

### 2

#### Description

Intervention group: Resistance training group with placebo

#### Category

Other

### 3

#### Description

Intervention group: Resistance training with ginger

#### Category

Other

### 4

#### Description

Intervention group: Ginger Group

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Diabetes Mellitus Association of Shahid Motahari Clinic

##### Full name of responsible person

Masoumeh Akhlaghi

##### Street address

Shiraz, Zand Avenue, opposite the Palestine Street, Central Building of Shiraz University of Medical Sciences

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##### Postal code

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##### Phone

+98 71 3233 7855

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##### Email

president@sums.ac.ir

##### Web page address

<https://www.sums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

semnan university

##### Full name of responsible person

seyed mohsen avandi

##### Street address

Semnan - Facing Sokan Park - Campus No. 1 - Central Organization of Semnan University

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**Province**

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**Postal code**

35131-19111

**Phone**

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**Fax**

+98 23 3332 1005

**Email**

president@semnan.ac.ir

**Web page address**<https://human.semnan.ac.ir/index.aspx?fkeyid=&siteid=25&pageid=3709>**Grant name**

Grant Assistant Professor Seyyed Mohsen Avandi

**Grant code / Reference number**

12

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

Yes

**Title of funding source**

semnan 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**

semnan university

**Full name of responsible person**

seyed mohsen avandi

**Position**

assistant professor of semnan university

**Latest degree**

Ph.D.

**Other areas of specialty/work**

exercise training

**Street address**Semnan - Opposite Sokan Park - Campus No. 1 -  
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**Web page address**<https://human.semnan.ac.ir/index.aspx?fkeyid=&siteid=25&pageid=3709>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

semnan university

**Full name of responsible person**

Seyed mohsen avandi

**Position**

Associate professor of semnan university

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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**Email**

president@semnan.ac.ir

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

semnan university

**Full name of responsible person**

hamzeh mohammadi

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Physiology

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**Email**

hamzeh.gh88@yahoo.com

**Web page address**

<https://human.semnan.ac.ir/index.aspx?fkeyid=&siteid=25&pageid=3709>

## 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**

The protocol was performed for two weeks in both pretest and post-test. You can access the data from Semnan University; Faculty of Humanities; Assistant Professor Seyyed Mohsen Adandi

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

2015 and 2020

**To whom data/document is available**

seyed mohsen avandi and hamzeh mohammadi

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

To help educate the community and students who want to continue the protocol

**From where data/document is obtainable**

University of Semnan - Faculty of Humanities - Department of Sport Physiology - Dr. Seyyed Mohsen Avadi

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

If requested, ask for one week to two weeks by email: hamzeh.gh88@yahoo.com

**Comments**

If you have not received an email, please call 09135603693.