

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

AgeFrom **40 years** old to **60 years** old**Gender**

Male

Phase

1

Groups that have been masked

- Participant

Sample sizeTarget 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

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

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

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Full name of responsible person

hamzeh mohammadi

Position

student

Latest degree

Master

Other areas of specialty/work

Physiology

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<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.