

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effects of supplementation with caffeine alone and in combination with aerobic training on some insulin resistance indices in patients with type 2 diabetes: a double-blind and placebo-controlled clinical trial

#### Protocol summary

##### Study aim

Determining the effect of caffeine supplementation alone and in combination with aerobic exercise will be some of the indicators of insulin resistance in patients with type 2 diabetes.

##### Design

Semi-experimental clinical trials with pre-test and post-test design

##### Settings and conduct

Tabriz University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Men with type 2 diabetes Being in the age range of 40-60 years, fasting blood sugar between 250-125 mg per deciliter, not suffering from diabetes-related diseases (such as neuropathy, nephropathy, retinopathy), lack of regular participation in regular exercise activities more than one session per week in For the past 3 months, not having blood pressure above 140.90 mm Hg and having more than a year of history will be a sign of diabetes.

##### Intervention groups

training group (TR) training and caffeine group (TR plus CA) caffeine group (CA) diabetic control group (C)

##### Main outcome variables

aerobic training; caffeine; leptin; adiponectin; insulin; glucose; HOMA-IR: QUICKI:HbA1C

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170116031982N2**

Registration date: **2020-04-24, 1399/02/05**

Registration timing: **prospective**

Last update: **2020-04-24, 1399/02/05**

Update count: **0**

##### Registration date

2020-04-24, 1399/02/05

##### Registrant information

###### Name

ali zarghami khameneh

###### Name of organization / entity

University of Tabriz

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 4246 2051

###### Email address

ali.zarghami@tabrizu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-20, 1399/03/31

##### Expected recruitment end date

2020-07-05, 1399/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of supplementation with caffeine alone and in combination with aerobic training on some insulin resistance indices in patients with type 2 diabetes: a double-blind and placebo-controlled clinical trial

##### Public title

Effects of caffeine and aerobic training on type 2 diabetes

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Fasting blood sugar between 250-125 mg / dL Lack of diabetes-related diseases (such as neuropathy, nephropathy, retinopathy) Lack of regular participation in regular physical activities more than one session per week during the last 3 months No blood pressure above 140/90 mm Hg

#### **Exclusion criteria:**

Complications of diabetes such as diabetic foot History of cardiovascular disease

### **Age**

From **50 years** old to **55 years** old

### **Gender**

Male

### **Phase**

2-3

### **Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### **Sample size**

Target sample size: **32**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Balanced block randomization

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

Participants are leading researchers, especially in trials initiated by RASA academic researchers, health care personnel (physicians, nurses, physiotherapists, etc.) who are responsible for patient care, data collection authorities and those.

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

##### **Street address**

Faculty of Nutrition and Food sciences, Tabriz University of Medical Sciences Attar Neishabouri St.,

Tabriz, I. R. Iran

#### **City**

Tabriz

#### **Province**

East Azarbaijan

#### **Postal code**

5384143841

#### **Approval date**

2020-02-03, 1398/11/14

#### **Ethics committee reference number**

IR.TBZMED.REC.1398.1179

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Type 2 diabetes

#### **ICD-10 code**

E08

#### **ICD-10 code description**

Diabetes mellitus due to underlying condition

## **Primary outcomes**

### **1**

#### **Description**

leptin

#### **Timepoint**

The first stage before the start of supplementation and training and the second stage 24 hours after the last training session

#### **Method of measurement**

The double-antibody sandwich ELISA

### **2**

#### **Description**

Adiponectin

#### **Timepoint**

The first stage before the start of supplementation and training and the second stage 24 hours after the last training session

#### **Method of measurement**

ELISA

## **Secondary outcomes**

### **1**

#### **Description**

Glucose

#### **Timepoint**

The first stage before the start of supplementation and training and the second stage 24 hours after the last training session

#### **Method of measurement**

Glucose oxidase methods

## 2

### **Description**

Insulin

### **Timepoint**

The first stage before the start of supplementation and training and the second stage 24 hours after the last training session

### **Method of measurement**

Competitive ELISA

## 3

### **Description**

Homeostatic model assessment (HOMA)

### **Timepoint**

The first stage before the start of supplementation and training and the second stage 24 hours after the last training session

### **Method of measurement**

Fasting serum insulin ( $\mu\text{U/ml}$ )  $\times$  fasting plasma glucose ( $\text{mmol/l}$ )/22.5

## 4

### **Description**

Quantitative Insulin Sensitivity Check Index

### **Timepoint**

The first stage before the start of supplementation and training and the second stage 24 hours after the last training session

### **Method of measurement**

$1 / (\log(\text{fasting insulin } \mu\text{U/mL}) + \log(\text{fasting glucose mg/dL})) = \text{QUICKI}$

## **Intervention groups**

### 1

#### **Description**

Intervention group: The first intervention group 8 weeks of walking on the treadmill with a slope of zero degrees for 40 minutes with an intensity of 70-60% heart rate reserve for three days per week

#### **Category**

Prevention

### 2

#### **Description**

Intervention group: The second intervention group consumed 3 mg per kg body weight per day of caffeine capsules for 8 weeks

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Faculty of Nutrition and Food Sciences

#### **Full name of responsible person**

Alireza ostadrahimi

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

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#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tabriz University of Medical Sciences

#### **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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Bahram jamali garakhanlu  
**Position**  
Associate professor  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**

## 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

Not applicable

### Data Dictionary

Yes - There is a plan to make this available

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

Only a part of the data, such as information about the main consequence or the like, can be shared.

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

Starting available 6 months after the publication of results

### To whom data/document is available

For researchers working in academic and scientific institutions and people who are also engaged in industry.

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

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### From where data/document is obtainable

alireza ostadrahimi ostadrahimi@tbzmed.ac.ir bahram jamali 09143035484

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

As soon as possible, contact the respondents related to the project

### Comments