

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)

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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

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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 (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 perweek

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

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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

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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
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