

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Studing the effects of Epigallocatechin Gallate supplementation on lipid profile, Insulin resistance, Oxidative stress and inflammatory factors in rs9939609 FTO gene variants in type 2 diabetic patients.

Protocol summary

Summary

The purpose of this study is to assess the effect of Epigallocatechin Gallate supplementation on lipid profile, Insulin resistance, Oxidative stress and inflammatory factors in rs9939609 FTO gene variants in type 2 diabetic patients. In this randomized, double blind, placebo controlled trial with parallel design, 92 patients suffering from type 2 diabetes will be selected among patients referring to diabetes Clinic of Golestan Hospital in Ahvaz. Participants will be randomly assigned to intervention or control group (1:1 ratio) based on the blocked randomization method. The intervention and control groups respectively will be received Epigallocatechin Gallate capsules (2 × 150 mg per day) and Nokhodchi flour capsules (2 × 150 mg per day) as placebo for 8 weeks. Inclusion criteria include Patients aged between 20 to 40 years who will be diagnosed with type 2 diabetes. Exclusion criteria for the study will be alcohol consumption; smoking; pregnant and lactating women; injection insulin and Taking anti inflammatory drugs. At the beginning and end of the study different variables of the study include levels of lipid profile, oxidative stress, inflammatory factors and FTO gene variants will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021612949N3**
Registration date: **2017-04-04, 1396/01/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-04, 1396/01/15

Registrant information

Name

Meysam Alipour

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studing the effects of Epigallocatechin Gallate supplementation on lipid profile, Insulin resistance, Oxidative stress and inflammatory factors in rs9939609 FTO gene variants in type 2 diabetic patients.

Public title

Effect of Epigallocatechin Gallate supplementation on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Men or women aged between 20 to 60 years old, Minimum 2 years experience in diabete.

Exclusion criteria: Alcohol consumption; smoking; Pregnant and lactating women; injection insulin; Taking anti inflammatory drugs; Using nutrition supplements; Hormone Therapy; Patients with a history of hypothyroidism; renal failure.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address

Golestan Ave, Ahvaz, Ahvaz Jundishapur University of Medical Sciences, Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

City

Ahvaz

Postal code

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

IR.AJUMS.REC.1395.548

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus Type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Lipid profile (TG, LDL, HDL, Total cholesterol)

Timepoint

Before and after 8 weeks intervention

Method of measurement

Mg/dl, laboratory kit

2

Description

Serum Total Anti Oxidant Capacity (TAOC)

Timepoint

Before and after 8 weeks intervention

Method of measurement

ELISA

3

Description

High sensitive C reactive protein

Timepoint

Before and after 8 weeks intervention

Method of measurement

ELISA

4

Description

Interleukin 6

Timepoint

Before and after 8 weeks intervention

Method of measurement

ELISA

5

Description

Fasting Blood Sugar (FBS)

Timepoint

Before and after 8 weeks intervention

Method of measurement

Mg/dl, laboratory kit

6

Description

Insulin

Timepoint

Before and after 8 weeks intervention

Method of measurement

ELISA

7

Description

Insulin Resistance (IR)
Timepoint
Before and after 8 weeks intervention
Method of measurement
Based on HOMA IR equation

Secondary outcomes

1
Description
Body Mass Index (BMI)
Timepoint
Before and after 8 weeks intervention
Method of measurement
Weight (kilograms) divided by the square of height (meters)

2
Description
Sistolic and diastolic blood pressure
Timepoint
Before and after 8 weeks intervention
Method of measurement
By mercury sphygmomanometer

Intervention groups

1
Description
All patients will receive 300 mg (2×150mg) epigallocatechin Gallate capsules for 8 weeks.
Category
Treatment - Drugs

2
Description
All patients will receive 300 mg (2×150 mg) placebo capsules (Nokhodchi flour) for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Ahvaz Golestan Hospital Clinic
Full name of responsible person
Dr. Mehrnoosh zakerkish
Street address
Ahvaz Jundishapur University of Medical Sciences
City
Ahvaz

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr.Behzad Sharif Makhmalzadeh, Deputy of research development
Street address
Golestan Ave, Ahvaz, Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences
Ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Meysam Alipour
Position
PhD student of Nutrition
Other areas of specialty/work
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Person responsible for scientific

inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty