Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Meysam Alipour
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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 cholestrol)

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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Fax

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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