

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effects of Epigallocatechin Gallate Supplementation on the Insulin Resistance and Inflammatory Factors in Patients with Type 2 Diabetes

Protocol summary

Study aim

Assess the effect of Epigallocatechin Gallate supplementation on Insulin resistance and inflammatory factors in type 2 diabetic patients.

Design

At the beginning and end of the study different variables of the study include levels of Insulin resistance and inflammatory factors will be measured.

Settings and conduct

In this randomized, double blind, placebo controlled trial with parallel design, 50 patients suffering from type 2 diabetes will be selected among patients referring to diabetes Clinic of 501 Hospital in Tehran. Participants will be randomly assigned to intervention or control group (1:1 ratio) based on the blocked randomization method.

Participants/Inclusion and exclusion criteria

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.

Intervention groups

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.

Main outcome variables

Insulin resistance and hscrp

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181219042047N1**

Registration date: **2019-02-13, 1397/11/24**

Registration timing: **retrospective**

Last update: **2019-02-13, 1397/11/24**

Update count: **0**

Registration date

2019-02-13, 1397/11/24

Registrant information

Name

said hadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8609 6350

Email address

s.hadinu@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

2018-06-22, 1397/04/01

Scientific title

Effects of Epigallocatechin Gallate Supplementation on the Insulin Resistance and Inflammatory Factors in Patients with Type 2 Diabetes

Public title

Effect of Epigallocatechin Gallate supplementation on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

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

Exclusion criteria:

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

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are categorized and are randomly assigned to the soy Epigallocatechin Gallate or placebo group. To randomly assign patients to the two groups, a Stratified Blocked Randomization method is used. Randomization is concealed in sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind (investigators and patients) trial. For double-blind implementation, at the beginning of the study, all boxes containing soybean Epigallocatechin Gallate or placebo by a third party (someone other than the researchers) is coded as A and B

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of AJA University Of Medical Sciences

Street address

AJA University Of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2018-12-09, 1397/09/18

Ethics committee reference number

IR.AJAUMS.REC.1397.063

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**

High sensitive C reactive protein

Timepoint

Before and after 8 weeks intervention

Method of measurement

ELISA

2**Description**

Fasting Blood Sugar (FBS)

Timepoint

Before and after 8 weeks intervention

Method of measurement

Mg/dl, laboratory kit

3**Description**

Insulin

Timepoint

Before and after 8 weeks intervention

Method of measurement

ELISA

4**Description**

Insulin Resistance (IR)

Timepoint

Before and after 8 weeks intervention

Method of measurement

Based on HOMA IR equation

5

Description

Body Mass Index (BMI)

Timepoint

Before and after 8 weeks intervention

Method of measurement

Weight (kilograms) divided by the square of height (meters)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients will receive 300 mg (2×150mg) epigallocatechin Gallate capsules for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: 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

501 Hospital Clinic

Full name of responsible person

Said Hadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mostafa Shahrezayee

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Said hadi

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available