Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Epigallocatechin Gallate Supplementation on the Insulin Resistence 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 Resistence 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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AJA University Of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran
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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
Street address
AJA University Of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran
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moshahrezayee@yahoo.com
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 updating data

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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