

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of genistein supplementation on metabolic parameters and oxidative stress in postmenopausal women with type 2 diabetes.

Protocol summary

Summary

The objective of this randomized double-blind placebo controlled trial is to investigate the effect of genistein supplementation on indicators of blood glucose, serum lipid profile, oxidative stress status in postmenopausal women with type-2 diabetes. postmenopausal women with type-2 diabetes, will be recruited from Doctor Gholipour Hospital in Boukan including 60 individual. Subjects will be randomly assigned to receive either 54mg genistein oral tablet or placebo tablets for 3 month. Anthropometric measurements (weight, height, waist and hip circumference, waist to hip ratio) and biochemical parameters (lipid profile including total cholesterol, LDL and HDL cholesterol and triglyceride concentrations, fasting glucose and insulin level, HbA1C, and TAC, MDA levels), As well as insulin resistance and insulin sensitivity will be evaluated by using HOMA-IR and QUICKI index respectively. dietary data obtained from 3-day food records will be measured before and after treatment and compared between groups. And the data will be analyzed by using appropriate statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611033664N18**

Registration date: **2017-01-31, 1395/11/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-31, 1395/11/12

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

rafradm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor Of Research Tabriz University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of genistein supplementation on metabolic parameters and oxidative stress in postmenopausal women with type 2 diabetes.

Public title

The effect of genistein supplementation on metabolic parameters and oxidative stress in postmenopausal women with type 2 diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in the study; Postmenopausal women with history of at least one year menopause ; menopause must not be a complication of

surgery; Type-2 diabetes for at least 6 months; using blood glucose lowering drugs (metformin) . Exclusion criteria: Unwillingness to participate in the study; Surgery leads to menopause; Early menopause (before 40 years); Use of androgen and estrogen and other steroids can affect the estrogen receptor; Insulin injections; Use of any nutritional supplements (omega-3) or anti-inflammatory and antioxidant supplements in the last 3 months or during the study; Liver and kidney failure, cardiovascular disease, breast cancer and thyroid disease; Smoking and alcohol; Patients taking NSAID, corticosteroids (prednisone, methylprednisolone, and hydrocortisone), antidiuretic thiazide (furosemide and hydrochlorothiazide) and anti psychotics second generation (olanzapine, clozapine and). (All participants in the study shouldn't take these drugs at least three months before the study)

Age

From **45 years** old to **64 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Tabriz University of Medical Science

Street address

Golgasht Street, Tabriz University of Medical Sciences, East Azarbayjan

City

Tabriz

Postal code**Approval date**

2016-12-05, 1395/09/15

Ethics committee reference number

IR.TBZMED.REC.1395.925

Health conditions studied**1****Description of health condition studied**

type 2 diabetes

ICD-10 code

E,11

ICD-10 code description

Non-insulin-dependent type 2 diabetes

Primary outcomes**1****Description**

Indicators Blood Sugar (FBS, HbA1C, fasting insulin, insulin resistance and insulin sensitivity)

Timepoint

Before and after intervention

Method of measurement

Fasting blood glucose by Spectrophotometry, serum insulin by ELISA and serum HbA1C measurements will be done by ion-exchange chromatography. As well as insulin resistance (HOMA-IR) and insulin sensitivity (QUICKI) will be calculated from formulas.

2**Description**

Serum lipid profile (TG, TC, HDL-C, LDL-C)

Timepoint

Before and after the intervention.

Method of measurement

Measuring TG, TC and HDL-C were performed using spectrophotometric methods. LDL-C levels were determined using the formula Fried-Wald.

3**Description**

Oxidative Stress (MDA, TAC)

Timepoint

Before and after the intervention.

Method of measurement

TAC and MDA measurements will be performed using spectrophotometry.

4**Description**

Weight, BMI, waist circumference, hip circumference and waist-to-hip ratio

Timepoint

Before and after the intervention.

Method of measurement

Body weight will be measured without shoes and with minimal coverage by Seca scales with an accuracy of 0.1 kg Height, waist and hip are also measured by inelastic meters with an accuracy of 0.5 cm. For calculate of BMI will be used, $BMI = \text{weight (kg)}/\text{height (cm)}^2$ and , waist-to-hip ratio was calculated, $WHR = \text{waist} / \text{hip}$.

Secondary outcomes

1

Description

physical activity

Timepoint

before and after the intervention

Method of measurement

Physical Activity Questionnaire ipaq

2

Description

Energy and macronutrients intakes (carbohydrates, proteins and fats)

Timepoint

before, End of sixth week and after the intervention

Method of measurement

Dietary record

Intervention groups

1

Description

Placebo groups: Placebo, 54 mg/day for 3 month

Category

Placebo

2

Description

Intervention Group: 54 mg/day in two capsules for 3 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital outpatient clinic Doctor Gholipour

Full name of responsible person

Hassan Braxas

Street address

City

Boukan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Tabriz Nutrition Research Center, Tabriz University of Medical Science

Full name of responsible person

Maryam Rafrat

Street address

Health and Nutrition school, Attare Neishabouri avenue, Golgasht street

City

Tabriz

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, Tabriz Nutrition Research Center, Tabriz University of Medical Science

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

Tabriz University Of Medical Sciences

Full name of responsible person

Hassan Braxas

Position

MS student in Nutrition

Other areas of specialty/work

Street address

Health and Nutrition school, Attare Neishabouri Avenue, Golgasht street, Tabriz

City

Tabriz

Postal code

Phone

+98 44 4625 1716

Fax

Email

h.nippon@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hassan Braxas

Position

MSc Student of Nutrition Science

Other areas of specialty/work

Street address

Attar Neyshabouri Street, Golgasht Street, Nutrition Faculty, Tabriz

City

Tabriz
Postal code
Phone
+98 44 4625 1716
Fax
Email
h.nippon@yahoo.com
Web page address

Postal code
Phone
+98 44 4625 1716
Fax
Email
h.nippon@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Hassan Braxas
Position
MSc Student of Nutrition Science
Other areas of specialty/work
Street address
Health and Nutrition school, Attare Neishabouri
Avenue, Golgasht street
City
Tabriz

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