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

rafrafm@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 Scince

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 = weight (kg)/height (cm)2 and , waist-to-hip ratio was calculated, WHR = waist / 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 for3 month
Category
Placebo

2

Description
Intervention Group: 54 mg/day in two capsule 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 Rafraf
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 Sciense
Other areas of specialty/work
Street address
Attar Neyshabori Street, Golgasht Street, Nutrition Faculty, Tabriz
City

Tabrize
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 Sciense
Other areas of specialty/work
Street address
Health and Nutrition school, Attare Neishabouri Avenue, Golgasht street
City
Tabriz
Postal code
Phone
+98 44 4625 1716
Fax
Email
h.nippon@yahoo.com
Web page address

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