Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Effect of genistein supplementation on serum level of homocystein and PAI-1 (Plasminogen Activator Inhibitor-1) in postmenopausal women with type-2 diabetes mellitus.

Protocol summary

Study aim
Determining the effect of genistein supplementation on serum level of homocystein and PAI-1 in postmenopausal women with type-2 diabetes mellitus.

Design
Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables.

Settings and conduct
The aim of this study was to evaluate the effect of genistein supplementation on homocysteine and PAI-1 status in patients with T2DM. For each person, the general characteristics questionnaire, anthropometric evaluations, Food registration and IPAQ will be completed. To measure all biochemical parameters, 10 cc of venous blood is collected fast (at the beginning and end of the study). and their serum will be separated and kept at -70° until testing

Participants/Inclusion and 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: Surgery leads to menopause; Early menopause; 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, antidiuretic thiazide and anti psychotics second generation.

Intervention groups
group 1 receiving genistein (2 capsule 54 mg), group 2 placebo group (2 capsule 54 mg placebo)

Main outcome variables
serum level of homocysteine and PAI-1

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100408003664N23**
Registration date: **2018-10-30, 1397/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-30, 1397/08/08**
Update count: **0**

Registration date
2018-10-30, 1397/08/08

Registrant information

Name
Maryam Rafraf

Name of organization / entity
Tabriz University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of genistein supplementation on serum level of homocystein and PAI-1 (Plasminogen Activator Inhibitor-1) in postmenopausal women with type-2 diabetes mellitus.

Public title

Effect of genistein supplementation on serum level of homocystein and PAI-1 (Plasminogen Activator Inhibitor-1) in postmenopausal women with type-2 diabetes mellitus.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Postmenopausal women with history of at least one year menopause 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)

Age

From **45 years** old to **67 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups.A random sequence is generated using the STATA14 software.During the random assignment, individuals in the groups will be classified according to age and BMI variables.

Blinding (investigator's opinion)

Double blinded

Blinding description

the placebo and supplement will be packed in the same number in similar packages. The method of blindness will be that the supplements and placebo will be delivered to the participants by someone other than the researcher, and the researcher will remain unaware until the end of the study.

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

Tabriz University of Medical Science, Attar Neishabouri Avenue, Golgasht street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Approval date

2018-08-27, 1397/06/05

Ethics committee reference number

IR.TBZMED.REC.1397.462

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11.-

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

homocysteine

Timepoint

Before the intervention and 12 weeks after starting

Method of measurement
ELISA

2

Description
PAI-1
Timepoint
Before the intervention and 12 weeks after starting
Method of measurement
ELISA

Secondary outcomes

1

Description
Physical activity
Timepoint
Beginning and end of intervention
Method of measurement
International Assessment of Physical Activity (IPAQ) questionnaire

2

Description
Diet
Timepoint
First, middle and end of study
Method of measurement
3-day food record

Intervention groups

1

Description
Intervention group: 54 mg/day genistein supplement in two capsule for 3 month
Category
Treatment - Drugs

2

Description
Control group: 54 mg/day placebo in two capsule for 3 month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital outpatient clinic Doctor Gholipour
Full name of responsible person
Hassan Braxas
Street address
Shohada boulevard
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5951678467
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+98 44 4623 5701
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Hit.boukan@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutritional Reseach Center of Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostadrahimi
Street address
Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street
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nut-rc@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutritional Reseach Center of Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
hassan Braxas
Position

MS student in Nutrition

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Position
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Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available