

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

rafrafm@tbzmed.ac.ir

##### 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

## City

Boukan

## Province

West Azarbaijan

## Postal code

5951678467

## Phone

+98 44 4623 5701

## Email

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

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614711

#### Phone

+98 41 3336 3430

#### Email

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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Health and Nutrition school, Attare Neishabouri Avenue, Golgasht street

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**Person responsible for scientific 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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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

MS student in Nutrition

**Latest degree**

Bachelor

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**Phone**

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**Email**

h.nippon@yahoo.com

**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