

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of menaquinone (MK-7) supplementation on metabolic, nutritional, inflammatory status and matrix $\gamma$ -carboxyglutamate protein in DMII

#### Protocol summary

##### Study aim

The aim of present study is to determine the effect of menaquinone supplementation (MK-7) on metabolic, nutritional, inflammatory, and matrix  $\gamma$ -carboxyglutamate protein in people with type II diabetes.

##### Design

double blind randomized controlled trial, with parallel groups

##### Settings and conduct

Design of the study is a double-blind randomized controlled clinical trial with placebo and duration of intervention is 12 weeks. A total of 46 patients with type II diabetes will be included in the study after reviewing inclusion and exclusion criteria. At the beginning of the study, the dietary advice will be made available to all people according to the guidelines of the American Diabetes Association. Then subjects will enter in two groups of menaquinone and placebo. Demographic questionnaire will be completed at the beginning of the study but physical activity questionnaire (IPAQ), 3-day food record, anthropometric indices and body composition will be done at the end of the study. Also, at the beginning and the end of the study, 7 cc of venous blood will be taken and metabolic, nutritional, inflammatory and vitamin K level indices will be measured.

##### Participants/Inclusion and exclusion criteria

In this study, non-menopausal women and men aged 20-55 years old and BMI of 27-35 with type 2 diabetes who control their disease with anti-diabetes drugs will be included in the study but insulin users or presence of any factors that affect the vitamin K status in the body will not be included in the study.

##### Intervention groups

The intervention and non-intervention group for three months will consume menaquinone supplement (200 mcg/day) and placebo (containing Microcrystalline cellulose), respectively.

##### Main outcome variables

Glycemic indexes, lipid profile, anthropometric and body composition indices, inflammatory status indicators, indicators of vitamin K status

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100123003140N22**

Registration date: **2019-05-20, 1398/02/30**

Registration timing: **prospective**

Last update: **2019-05-20, 1398/02/30**

Update count: **0**

##### Registration date

2019-05-20, 1398/02/30

##### Registrant information

##### Name

Bahram Pourghassem Gargari

##### Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1435 7580

##### Email address

pourghassemb@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-08, 1398/03/18

##### Expected recruitment end date

2019-10-10, 1398/07/18

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Effect of menaquinone (MK-7) supplementation on metabolic, nutritional, inflammatory status and matrix  $\gamma$ -carboxyglutamate protein in DMII

**Public title**  
Effect of menaquinone supplementation in DMII

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Men and non-postmenopausal women, With type 2 diabetes (at least from 6 months prior to the study), With desire to participate in the study, Age of 20-55 years, BMI 27-35 kg/m<sup>2</sup>, Who use anti diabetic drugs.  
**Exclusion criteria:**  
Pregnancy, lactation, menopause, hormone therapy, use of vitamin K containing contraceptives, polycystic ovary syndrome; Presence of diseases affecting vascular calcification or cardiac dysfunction; History of bone, rheumatoid arthritis, thyroid, parathyroid, liver, kidney, intestine disease or malignancies; Presence of infectious or inflammatory disease symptoms or recent surgery; Use of insulin, corticosteroids and anticoagulant drugs such as warfarin and coumarin; Adherence to a specific diet and consumption of any dietary supplements or weight reducing drugs for 3 month prior to the study; Smoking.

**Age**  
From **20 years** old to **55 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **46**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Participants in the study will be divided into two groups using balanced block randomization: 1) menaquinone tablet consumer 2) placebo consumer First, the quadruple Blocks and arrangement of blocks with their numbering will be determined. Then after selection of specific blocks using a random number table and based on the number of blocks, entering the first four participants will be done. Then again, determination of the next block will be done using the random number table and this will continue until we reach the specified sample size.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, neither the participants nor the researcher know which participants belong to the treatment group and which belong to the non-treatment group.

**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 Sciences

##### Street address

No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

#### Approval date

2019-04-25, 1398/02/05

#### Ethics committee reference number

IR.TBZMED.REC.1398.123

## Health conditions studied

### 1

#### Description of health condition studied

Type II Diabetes

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

Blood levels of fasting glucose

#### Timepoint

Before and after the intervention

#### Method of measurement

Enzymatic method

### 2

#### Description

Blood levels of fasting insulin

**Timepoint**

Before and after the intervention

**Method of measurement**

ELIZA KIT

**3****Description**

Serum levels of HbA1c

**Timepoint**

Before and after the intervention

**Method of measurement**

Spectrophotometry

**4****Description**

Insulin resistance index

**Timepoint**

Before and after the intervention

**Method of measurement**

Formula

**5****Description**

Blood levels of triglycerides

**Timepoint**

Before and after the intervention

**Method of measurement**

Enzymatic method

**6****Description**

Blood levels of total cholesterol

**Timepoint**

Before and after the intervention

**Method of measurement**

Enzymatic method

**7****Description**

Blood levels of HDL-cholesterol

**Timepoint**

Before and after the intervention

**Method of measurement**

Enzymatic method

**8****Description**

Blood levels of LDL-cholesterol

**Timepoint**

Before and after the intervention

**Method of measurement**

Friedewald formula

**9****Description**

Anthropometric indices

**Timepoint**

Before and after the intervention

**Method of measurement**

Scale, Stadiometer, Tape

**10****Description**

Body composition indices

**Timepoint**

Before and after the intervention

**Method of measurement**

Impedance bio-electric system

**11****Description**

Serum levels of TNF- $\alpha$

**Timepoint**

Before and after the intervention

**Method of measurement**

ELIZA KIT

**12****Description**

Serum levels of hsCRP

**Timepoint**

Before and after the intervention

**Method of measurement**

ELIZA KIT

**13****Description**

Serum levels of IL-6

**Timepoint**

Before and after the intervention

**Method of measurement**

ELIZA KIT

**14****Description**

Blood levels of dpucMGP

**Timepoint**

Before and after the intervention

**Method of measurement**

ELIZA KIT

**15****Description**

Blood levels of PIVKAll

**Timepoint**

Before and after the intervention

**Method of measurement**

ELIZA KIT

**Secondary outcomes****1****Description**

Dietary intake  
**Timepoint**  
Before and after the intervention  
**Method of measurement**  
Three day food record questionnaire

## 2

**Description**  
physical activity level  
**Timepoint**  
Before and after the intervention  
**Method of measurement**  
IPAQ questionnaire

## Intervention groups

### 1

**Description**  
Intervention group: menaquinone supplement (in the form of MK-7), will be taken at a single daily dose of 200 microgram along with the main meal for a period of three months. The pure menaquinone supplement (DELTA, product of Kappa Bioscience AS, Norway, Denmark) will be introduced by Iran-based Mahbān-Daroo and supplement tablets will be provided by the professors of the School of Pharmacy.

**Category**  
Other

### 2

**Description**  
Control group: a single placebo tablet (containing microcrystalline cellulose) will be taken along with the main meal for a period of three months. Placebo tablets will be provided by the professors of the School of Pharmacy so that their shape and appearance look exactly like tablets of intervention group.

**Category**  
Placebo

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Salamat Specialist Polyclinics of Tabriz  
**Full name of responsible person**  
Dr. Esmaeil Faraji  
**Street address**  
Nyayesh Blvd, between pishghadam and sajjadiye,  
Salamat Specialist Polyclinics of Tabriz  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5165741651  
**Phone**

+98 41 3325 9774  
**Email**  
nahidkaramzad@gmail.com  
**Web page address**  
<http://www.tabrizmodern.ir>

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr. Abolghasem Jouyban  
**Street address**  
No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614711  
**Phone**  
+98 41 3335 7310  
**Fax**  
+98 41 3334 4280  
**Email**  
ajouyban@hotmail.com  
**Web page address**  
<https://researchvice.tbzmed.ac.ir/page/5/%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D8%AA%D8%AD%D9%82%DB%8C%D9%82%D8%A7%D8%AA-%D9%88-%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C.html>  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
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**

Dr. Bahram Pourghassem Gargari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

□Faculty of Nutrition and Food Science, Tabriz  
University of Medical Sciences, Golghast Street,  
Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3336 2117

**Fax**

+98 41 3334 0634

**Email**

bahrampg@yahoo.com

**Web page address**

<http://www.scopus.com/authid/detail.url?authorId=8561353400>

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Bahram Pourghassem Gargari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition and Food Sciences, Tabriz  
University of Medical Sciences, Golghast Street,  
Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3336 2117

**Fax**

+98 41 3334 0634

**Email**

pourghassemb@tbzmed.ac.ir

**Web page address**

<http://www.scopus.com/authid/detail.url?authorId=8561353400>

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Bahram Pourghassem Gargari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition and Food Sciences, Tabriz  
University of Medical Sciences, Golghast Street,  
Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3336 2117

**Fax**

+98 41 3334 0634

**Email**

bahrampg@yahoo.com

**Web page address**

<http://www.scopus.com/authid/detail.url?authorId=8561353400>

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

All data

**When the data will become available and for how long**

After completing the study and publishing the articles

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

With the permission of the researcher and sponsor of the project

**From where data/document is obtainable**

Project researchers  
**What processes are involved for a request to access data/document**

email or phone call  
**Comments**