

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of menaquinone (MK-7) supplementation on metabolic, nutritional, inflammatory status and matrix γ -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 γ -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)

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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 γ -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/m², 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- α

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 PIVKAI

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Bahram Pourghassem Gargari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Other areas of specialty/work

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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