Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 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-carboxyglutamat 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 manaquinone 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 indicies 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 manaquinone 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

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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

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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 cholestrol
Timepoint
Before and after the intervention
Method of measurement
Enzymatic method

7

Description
Blood levels of HDL-cholestrol
Timepoint
Before and after the intervention
Method of measurement
Enzymatic method

8

Description
Blood levels of LDL-cholestrol
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 PIVKAII
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

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Full name of responsible person

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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 updating data

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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

email or phone call

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

Comments