

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Effects of vitamin K2 (MK-7) oral supplementation on glycemic control and lipid profile in individuals with type 2 diabetes: A double-blind randomized clinical trial

Protocol summary

Study aim

Effects of vitamin K2 (MK-7) oral supplementation on glycemic control and lipid profile in individuals with type 2 diabetes

Design

A clinical trial with control, parallel group, double blinded, randomized

Settings and conduct

Eligible individuals are selected from diabetes clinics of Shahid Beheshti hospitals who are volunteer to participate in the study by using data collection form. Allocation concealment is simple and individually. All the participants and the researchers were blinded to the treatment allocation. The research coordinator, the person who will not participate in the study, labeled these containers based on the codes of our randomized list.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes who have diabetes since 1 year ago and currently are treated only with oral glucose lowering medications. Based on laboratory results, their glycosylated hemoglobin should be between 6.5 and 10%. Exclusion criteria: Those who having allergy to vitamin K, pregnant and lactating women, and patients with cardiovascular, liver, and kidney diseases are not included in to the study. Insulin injection

Intervention groups

The intervention group will receive 180-mcg vitamin K2 capsules as a form of MK-7, twice daily after breakfast and dinner for 12 weeks (3 months). The placebo group will receive placebo capsules twice a day after breakfast and dinner for 12 weeks (3 months). Placebo capsules were filled with Avicel with identical appearance to the vitamin K. The vitamin K2 and placebo capsules were made by Arian Salamat Sina Pharmaceutical Company.

Main outcome variables

Fasting plasma glucose, Fasting plasma insulin, Glycated hemoglobin A1C, Insulin resistance indexes, Serum triglyceride, Serum total cholesterol, High-density lipoprotein, Low-density lipoprotein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190824044592N1**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

fatemeh rahimi sakak

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2243 2500

Email address

fatemeh.rahimisakak@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-26, 1398/07/04

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of vitamin K2 (MK-7) oral supplementation on glycemic control and lipid profile in individuals with type 2 diabetes: A double-blind randomized clinical trial

Public title
Effect of vitamin K2 (MK-7) in treatment of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients who have diabetes since 1 year ago Glycated hemoglobin between 6.5 and 10 % Not intake of Warfarin, Phenytoin, Phenobarbital, Dicoumarol, Phenprocoumon drugs Patients treating with oral lowering blood glucose medications
Exclusion criteria:
 Insulin injection Have chronic diseases such as heart, liver, kidney, cancer disease Having allergy to vitamin K Pregnancy or lactation

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the intervention and placebo groups were received code A or code B by the person who did not participate in the research (Project executives and patients do not know which group is A and which group is B). Then this person created quadratic blocks and in each block half of the blocks were group A and the other half were group B. She wrote 6 possible states of blocks on 6 pieces of paper (AABB-ABAB-ABBA-BBAA-BABA-BAAB) and then she put these six pieces in a container and she randomly selected one of these six papers from the container 17 times and note the composition written on it. Since our sample size was 68 people, she totally selected the blocks 17 times. Finally, an arrangement was made that during the intervention, it will be clear which group A or B belongs to each patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
All the participants and the researchers were blinded to the treatment allocation. Sixty vitamin K capsules or Sixty placebo capsules were placed into 204 identical

containers. 3 containers will be given to each patient during the intervention. The research coordinator, the person who will not participate in the study, labeled these containers based on the codes of our randomized list.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Research Institute for Endocrine Sciences of Shahid Beheshti University of Medicine
Street address
 No. 24, Aarabi Street, Yaman Street, Velenjak, Tehran
City
 Tehran
Province
 Tehran
Postal code
 1985717413

Approval date
2019-03-18, 1397/12/27

Ethics committee reference number
IR.SBMU.ENDOCRINE.REC.1398.011

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Glycated hemoglobin A1c

Timepoint
Glycated hemoglobin A1c will be measured at the beginning of the study and after 90 days of starting supplementation

Method of measurement
Enzymatic colorimetric method

2

Description

Fasting Plasma Insulin

Timepoint

Fasting Plasma Insulin will be measured at the beginning of the study (before the intervention) and after 90 days of starting supplementation .

Method of measurement

Enzyme-linked immunosorbent assay

3

Description

Fasting Plasma Glucose

Timepoint

Fasting Plasma Glucose will be measured at the beginning of the study (before the intervention) and after 90 days of starting supplementation.

Method of measurement

Enzymatic colorimetric method

4

Description

Insulin resistance indexes

Timepoint

Insulin resistance indexes will be calculated at the beginning of the study (before the intervention) and after 90 days of starting supplementation .

Method of measurement

Calculation

Secondary outcomes

1

Description

Serum Triglycerides

Timepoint

At the beginning and exactly at the end of intervention (90 days later)

Method of measurement

Enzymatic colorimetric method

2

Description

Serum cholesterol

Timepoint

At the beginning and exactly at the end of intervention (90 days later)

Method of measurement

Enzymatic colorimetric method

3

Description

High-density lipoprotein

Timepoint

At the beginning and exactly at the end of intervention (90 days later)

Method of measurement

Enzymatic colorimetric method

4

Description

Low-density lipoprotein

Timepoint

At the beginning and exactly at the end of intervention (90 days later)

Method of measurement

Enzymatic colorimetric method

Intervention groups

1

Description

Intervention group: After 12 h fasting, blood samples were collected at the beginning and end of week 12. Patients of this group will intake 180 mcg vitamin k2 (MK-7) twice daily after breakfast and dinner for 12 weeks. Phone calls were made to remind the participants about supplement consumption at the end of each week. Follow-up visits were carried out every 4 weeks while the supplements were delivered again. For dietary intake assessment, all of the participants were asked to record their dietary intakes for 3 days (one weekend day and two workdays) at baseline and end of the study. Vitamin K2 capsules were produced by Ariansalamat Sina pharmaceutical company, Iran.

Category

Treatment - Drugs

2

Description

Control group: After 12 h fasting, blood samples were collected at the beginning and end of week 12. Patients of this group will intake placebo of vitamin K2 capsules twice daily after breakfast and dinner for 12 weeks. Phone calls were made to remind the participants about supplement consumption at the end of each week. Follow-up visits were carried out every 4 weeks while the supplements were delivered again. For dietary intake assessment, all of the participants were asked to record their dietary intakes for 3 days (one weekend day and two workdays) at baseline and end of the study. Placebo of vitamin K2 capsules were produced by Ariansalamat Sina pharmaceutical company, Iran. Placebo capsules were filled with Avicel with identical appearance to the vitamin K

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Fatemeh Rahimi Sakak

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Aarabi st, Yaman st, Velenjak, Chamran highway,
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2

Recruitment center

Name of recruitment center

Tajrish Shohada Hospital

Full name of responsible person

Fatemeh Rahimi Sakak

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Shohadae Tajrish Hospital, Tajrish Sq, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Endocrine Sciences, Shahid
Beheshti University of Medical Sciences

Full name of responsible person

Fereidoun Azizi

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azizi@erc.ac.ir

Web page address

<https://www.endocrine.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Institute for Endocrine Sciences, Shahid
Beheshti 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

Research Institute for Endocrine Sciences, Shahid
Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Moslehi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nutrition Sciences and Food Technology,
Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Fatemeh Rahimi sakak

Position

Student

Latest degree

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Other areas of specialty/work

Nutrition

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Tehran, Iran

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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable