Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 tial

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 cods 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 lipoproteinn, 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)

Phone

+98 21 2243 2500

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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 tial

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 cods 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 Reseearch Institute for Endocrine Sciencs of Shahid Beheshti University of Medic

Street address

No. 24, Aarabi Street, Yaman Street, Velenjak, Tehran

City

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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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Recruitment center

Name of recruitment center
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Full name of responsible person
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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
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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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Full name of responsible person
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Person responsible for updating data

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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