

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Determination of the effect of vitamin D-fortified milk on serum vitamin D, glycemic control, lipid profile, anthropometric measurements, and blood pressure in people with type 2 diabetes

Protocol summary

Summary

The purpose of this study is determination the effect the effect of vitamin D-fortified milk on serum vitamin D, glycemic control, lipid profile, anthropometric measurements, and blood pressure in people with type 2 diabetes. Inclusion criteria: type 2 diabetes; without insulin therapy; without calcium and vitamin D supplementation in the last 3 months; not having liver and kidney failure; not having malabsorption of fat (fatty diarrhea); Not taking medications that affect vitamin D metabolism; lack of blood triglyceride lowering drugs; not having difficulty in eating 1 cup of milk per day. Exclusion criteria: Change the dose of glucose-lowering drugs; taking Calcium and vitamin D supplements during the study; Loss of more than 2 cups of milk a week , insulin therapy. The study population are patients with type 2 diabetes and the sample size is 102 persons. The study is Double blind and Blindness will be done in patients and researchers groups. Participants will randomly classify into two groups. The intervention and control groups has a cup of low fat milk fortified with vitamin D and a cup of low fat milk daily, respectively. During the intervening period is 9 weeks. In this period, dietary intakes will be check by 24-hours recall and dietary record. Before and after the intervention, blood sample will be taken to assess the changes (lipid profile and glycemic status , serum vitamin D, calcium and insulin levels).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021721120N1**
Registration date: **2015-05-10, 1394/02/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-10, 1394/02/20

Registrant information

Name

Saede Salehi

Name of organization / entity

Shiraz University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Science

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of the effect of vitamin D-fortified milk on serum vitamin D, glycemic control, lipid profile, anthropometric measurements, and blood pressure in people with type 2 diabetes

Public title

The effect of vitamin D-fortified milk on diabetes control

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: type 2 diabetes; Maximum age 75 years; without insulin therapy; without calcium and vitamin D supplementation in the last 3 months; not having liver and kidney failure; not having malabsorption of fat (fatty diarrhea); no history of CVD; Not taking medications that affect vitamin D metabolism, such as PTH, estrogen and calcitonin; lack of blood triglyceride lowering drugs; light to moderate physical activity; not having difficulty in eating 1 cup of milk per day; Willingness to cooperate. Exclusion criteria: Unwillingness to cooperate; Change the dose of glucose-lowering drugs; taking Calcium and vitamin D supplements during the study; Changes in levels of physical activity; Failure to adhere to the recommendations on diet and physical activity; Loss of more than 2 cups of milk a week; insulin therapy

Age

To 75 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 102

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Science

Street address

Central Building of Shiraz University of Medical Sciences, Zand Ave. , Shiraz

City

Shiraz

Postal code**Approval date**

2015-02-04, 1393/11/15

Ethics committee reference number

CT-9370-7350

Health conditions studied**1****Description of health condition studied**

Dabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

fasting blood sugar

Timepoint

before intervention and after intervention

Method of measurement

blood test

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

Total cholesterol

Timepoint

before intervention, after intervention

Method of measurement

blood test

2**Description**

LDL cholesterol

Timepoint

before intervention, after intervention

Method of measurement

blood test

3**Description**

HDL cholesterol

Timepoint

before intervention, after intervention

Method of measurement

blood test

4**Description**

triglyceride

Timepoint

before intervention, after intervention

Method of measurement

blood test

5

Description

serum calcium

Timepoint

before intervention, after intervention

Method of measurement

blood test

6

Description

serum vitamin D

Timepoint

before intervention, after intervention

Method of measurement

blood test

7

Description

serum insulin

Timepoint

before intervention, after intervention

Method of measurement

blood test

8

Description

blood pressure

Timepoint

before intervention, 4 week after start of intervention, end of intervention

Method of measurement

mercury manometer

9

Description

weight

Timepoint

before intervention, 4 week after start of intervention, end of intervention

Method of measurement

digital scale

10

Description

waist circumference

Timepoint

before intervention, 4 week after start of intervention, end of intervention

Method of measurement

meter

11

Description

hip circumference

Timepoint

before intervention, 4 week after start of intervention, end of intervention

Method of measurement

meter

Intervention groups

1

Description

Intervention group: vitamin D-fortified low fat milk, 1 cup per day for 9 week

Category

Treatment - Other

2

Description

Control group: low fat milk, 1 cup per day for 9 week

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahmad Nader kazemi clinic

Full name of responsible person

Street address

Valiasr square - Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shiraz University of Medical Science

Full name of responsible person

Dr Mohamad hadi Imanie

Street address

Central Building of Shiraz University of Medical Science , Zand Ave. , Shiraz

City

shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Shiraz University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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Shiraz University of Medical Science

Full name of responsible person

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Position

Faculty member

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

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty