

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

The comparative study of the effect of fortified yogurt with vitamin D, plain yogurt and vitamin D supplement on Glycemic, lipid and anthropometric indices in people with pre-diabetes

Protocol summary

Summary

This study is a single blind placebo- control clinical trial that will be done to aim of comparative study of the effect of fortified yogurt with vitamin D, plain yogurt and vitamin D supplement on Glycemic, lipid and anthropometric indices in patients referred to Taleghani Hospital Diabetic Clinic that recently they have been diagnosed with pre-diabetes condition. Sampling will be done the based on inclusion criteria and available sampling, then samples place randomly in three interventions, including fortified yogurt (100cc/day) with 1000 IU Vitamin D receiving group, vitamin D supplement (1000 IU/day) receiving group, plain yoghurt (100cc/day) receiving group. Inclusion criteria, including full consent of the individual, 25-65 years old, not family history of diabetes, lack of other chronic diseases (coronary heart, liver, kidney, thyroid, parathyroid, malabsorption, ...) or special circumstances such as pregnancy and breastfeeding, avoiding the use of any supplements or drugs and no smoking. Exclusion criteria, including lack of interest in the continuation of cooperation, failure to follow the consumption of specified amount of fortified yogurt with vitamin D, plain yogurt and vitamin D supplement and require to use of oral anti diabetic drug. The Intervention will be done for three months, before and three months after intervention are evaluated glycemic, lipids and anthropometric indices. To collect the data will use of questionnaires, including demographic data and disease status, physical activity and food frequency questionnaire (FFQ). Also to collect anthropometric data will use of Body composition Analyzer .In order to investigation of the blood indices, including fasting blood glucose, HbA1c, 2h- OGTT, fasting insulin, vitamin D, ca, AST, ALT, TC, LDL-c, HDL-c and TG, will be take 10 cc of blood in the fasting state, before and three month after the intervention. The study is in the recruitment phase.

Blinding will be done to Analysts of data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102615111N2**

Registration date: **2017-02-24, 1395/12/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-24, 1395/12/06

Registrant information

Name

Seyyed Mostafa Nachvak

Name of organization / entity

kermanshah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1826 2005

Email address

m.nachrak@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah university of medical sciences Damdaran company of Dairy

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative study of the effect of fortified yogurt with vitamin D, plain yogurt and vitamin D supplement on Glycemic, lipid and anthropometric indices in people with pre-diabetes

Public title

The effect of vitamin D on prevention of Diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : Full consent of the individual, 25-65 years old, not family history of diabetes, lack of other chronic diseases (coronary heart, liver, kidney, thyroid, parathyroid, malabsorption, ...) or special circumstances such as pregnancy and breastfeeding, avoiding the use of any supplements or drugs and no smoking. Exclusion criteria :lack of interest in the continuation of cooperation, failure to follow the consumption of specified amount of fortified yogurt with vitamin D, plain yogurt and vitamin D supplement and require to use of oral anti diabetic drug.

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

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

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In This study receiving groups of fortified yogurt and plain yogurt and researchers will be blind about nature of yogurts. The random placement of subjects in intervention groups is based on the random numbers table.

Secondary Ids

empty

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

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Ethics Committee, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti blvd

City

Kermanshah

Postal code**Approval date**

2016-10-19, 1395/07/28

Ethics committee reference number

KUMS.REC.1395.447

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

Prediabetes

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes mellitus

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

HbA1c

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pishtazteb HbA1c Kit

2**Description**

2h-OGTT

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon OGTT Kit

3**Description**

Vitamin D

Timepoint

Befor and 3 month after of intervention

Method of measurement

Vitamin D MONOBIND Kit

4**Description**

Ca

Timepoint

Befor and 3 month after of intervention
Method of measurement
Pars azmon Calcium Kit

5

Description

Serum insulin

Timepoint

Befor and 3 month after of intervention

Method of measurement

Insulin MONOBIND Kit

6

Description

FBS

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon glucose kit

7

Description

T-chol

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon Cholesterol Kit

8

Description

LDL-c

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon LDL- c Kit

9

Description

HDL-c

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon HDL- c Kit

10

Description

TG

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon Triglyceride Kit

11

Description

ALT

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon ALT Kit

12

Description

AST

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon AST Kit

Secondary outcomes

1

Description

FBS

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon glucose kit

2

Description

Serum insulin

Timepoint

Befor and 3 month after of intervention

Method of measurement

Insulin MONOBIND Kit

3

Description

TG

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon Triglyceride Kit

4

Description

vitamin D

Timepoint

Befor and 3 month after of intervention

Method of measurement

Vitamin D MONOBIND Kit

5

Description

Ca

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon Calcium Kit

6

Description

HbA1c

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pishtazteb HbA1c Kit

7

Description

T-chol

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon Cholesterol Kit

8

Description

LDL-c

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon LDL- c Kit

9

Description

HDL-c

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon HDL- c Kit

10

Description

2h-OGTT

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon OGTT Kit

11

Description

ALT

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon ALT Kit

12

Description

AST

Timepoint

Befor and 3 month after of intervention

Method of measurement

Pars azmon AST Kit

Intervention groups

1

Description

Riched yogurt (100cc/day) with 1000 IU Vitamin D
reciving group Intervention Duration: 3 month

Category

Prevention

2

Description

vitamin D supplement (1000 IU/day) receiving group

Category

Prevention

3

Description

plain yoghurt (100cc/day) reciving group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Headari

Street address

Taleghani Hospital, Naft Square, Shahid Beheshti blvd

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Kermanshah University
of Medical Sciences

Full name of responsible person

Heidarian

Street address

Vice Chancellor for research, Building No. 2 of
Kermanshah University of Medical Sciences, Naft
Square, Shahid Beheshti blvd

City

Kermanshah

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, Kermanshah University of
Medical Sciences

Proportion provided by this source

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***2****Sponsor****Name of organization / entity**

Damdaran Company of Dairy

Full name of responsible person

Tabatabaei

Street address

Damdaran Company of Dairy, Damdaran blvd, Haft joy industrial rural districtn, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Damdaran Company of Dairy

Proportion provided by this source**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***Person responsible for general inquiries****Contact****Name of organization / entity**

Public Health faculty

Full name of responsible person

Roghayeh Mostafai

Position

MSC Student

Other areas of specialty/work**Street address**

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Fax**Email**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of Health

Full name of responsible person

Seyed Mostafa Nachvak

Position

PHD

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Other areas of specialty/work**Street address**

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Fax**Email**

r_mostafai@yahoo.com

Web page address**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