Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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
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Public Health faculty, Next to the Farabi Hospital, Dolat Abad blvd, Isar Square, Imam Hosein Exp
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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6719851351
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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