

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The role of vitamin D receptor (VDR) single nucleotide polymorphisms (SNPs) in efficacy of vitamin D-fortified yogurt drink on metabolic-, inflammatory - and oxidative stress indicators in type 2 diabetic patients

Protocol summary

Summary

This is a single-blind controlled trial on the possible effects of vitamin D receptor (VDR) polymorphisms on efficacy of vitamin D intake in the patients with type 2 diabetes mellitus (T2DM). Ninety T2DM patients will receive 250 ml yogurt drink fortified with 500 IU of vitamin D3 twice a day for 3 months. VDR Fok1 genotypes will be determined at the end of the study and the responses to vitamin D (metabolic, inflammatory and oxidative stress) will be compared between the three subgroups, i.e. FF, Ff and ff. To relate the possible changes in the indicators to the vitamin D intake, there will be a diabetic control group (n=30) who will receive the same amount of plain (unfortified) yogurt drink during the study period. The responses of the control group will be compared with those of 30 diabetic patients randomly selected from the fortified yogurt drink group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810223006N2**

Registration date: **2010-04-27, 1389/02/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-27, 1389/02/07

Registrant information

Name

Tirang Reza Neyestani

Name of organization / entity

National nutrition and food technology research institute

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

1- National Nutrition & Food technology Research Institute , Shaheed Beheshti University of Medical Sciences & Health Services 2- School of Public health, Tehran University of Medical Sciences

Expected recruitment start date

2009-12-11, 1388/09/20

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of vitamin D receptor (VDR) single nucleotide polymorphisms (SNPs) in efficacy of vitamin D-fortified yogurt drink on metabolic-, inflammatory - and oxidative stress indicators in type 2 diabetic patients

Public title

Vitamin D receptor polymorphism , vitamin D-fortified Yogurt drink, Type 2 Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Fasting blood glucose ≥ 126 , 2. BMI between 25 to 35 kg/m², 3. Age: 30-60 years old, 4.

Willingness to maintain current body weight for the duration of the study, 5. Willingness to maintain baseline lifestyle activities and routines for the duration of the study, 6. Willingness to avoid the use of all over-the-counter or prescription vitamins, dietary supplements, and herbal products during the study. Exclusion criteria: 1. History of cardiovascular disease, Gastrointestinal disease, Renal disease, Kidney stone, Hyperparathyroidism, 2. Receiving vitamin D or omega-3 supplement within the last three months, 3. Pregnancy , or lactation within the study period, 4. Receiving insulin or any drug for weight reduction, reducing serum cholesterol, 5. Any change in type /or dose of the current hypoglycemic medications,

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethical Committee of National Nutrition & Food technology Research Institute

Street address

No 46, Arghavan Gharbi, Farahzadi Blvd., Shahrak Qods (Gharb)

City

Tehran

Postal code

1981619573

Approval date

empty

Ethics committee reference number

035360

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

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

Improvement in Serum Vitamin D Status

Timepoint

3 Months

Method of measurement

Serum 25(OH)D Level

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

oxidative stress biomarkers

Timepoint

baseline and 3 month after intervention

Method of measurement

serum superoxide dismutase,glutathion, glutathion peroxidase, MDA, TAC

2**Description**

inflammatory biomarkers

Timepoint

Baseline and 3 month after intervention

Method of measurement

Serum CRP,IL-6 and IL-4 , TNF- α and IFN- γ concentrations in cell culture medium

3**Description**

bone biomarkers

Timepoint

baseline and 3 month after intervention

Method of measurement

serum magnesium,Phosphor, calcium, PTH,Osteocalcin

4**Description**

glycemic biomarkers

Timepoint

baseline and 3 month after intervention

Method of measurement

serum fasting glucose ,Insulin, HbA1C and Quiccki index

5

Description

anthropometric indicators

Timepoint

Baseline and 3 month after intervention

Method of measurement

Weight, Height, BMI, Hip Circumferences , Waist Circumferences, WHR

6

Description

albumin, total protein, BUN, AST, ALT, lipid profiles and uric acid

Timepoint

Baseline and 3 months after intervention

Method of measurement

Serum Albumin, Total protein, BUN, AST, ALT, Lipid profiles and Acid uric

7

Description

urinary albumin, calcium, magnesium, phosphorous and micro-albumin

Timepoint

baseline and 3 month after intervention

Method of measurement

Urinary concentrations of micro-albumin, calcium, magnesium and phosphorous

8

Description

blood pressure

Timepoint

baseline and 3 month after intervention

Method of measurement

systolic and diastolic blood pressure

Intervention groups

1

Description

Intervention Group: Yogurt drink Fortified with 500 IU Cholecalciferol per 250 ml in AA genotype subgroup

Category

Treatment - Other

2

Description

Intervention Group: Yogurt drink fortified with 500 IU cholecalciferol per 250 ml in aa genotype subgroup

Category

Treatment - Other

3

Description

Intervention Group: Yogurt drink fortified with 500 IU

cholecalciferol per 250 ml in Aa genotype subgroup

Category

Treatment - Other

4

Description

Control Group: Plain yogurt drink

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Diabetes Society

Full name of responsible person

Street address

46 Ramin Malakooti Street , Patris Lomumba

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition & Food Technology Research Institute, Shaheed Beheshti University of Medical Scie

Full name of responsible person

Dr Tirang Reza Neyestani

Street address

Number 46, West Arghavan St., Farahzad Blvd., Shahrak Qods

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Nutrition & Food Technology Research Institute, Shaheed Beheshti University of Medical Scie

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

School of Public Health, Tehran University of Medical Sciences

Full name of responsible person

Dr Abolghasem Djazayeri

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Nutrition & Biochemistry Departement, School of Public Health, Tehran University of Medical Sciences

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of Public Health, Tehran 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

Person responsible for general inquiries

Contact

Name of organization / entity

Public Health School, Tehran University of Medical Sciences

Full name of responsible person

Sakineh Shab-Bidar

Position

Ph.D. Student in Nutritional Sciences

Other areas of specialty/work

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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