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)

Phone

+98 21 2237 6471

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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
Improvment 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 Scociety
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

City
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

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Other areas of specialty/work

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Other areas of specialty/work

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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