Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Comparison of efficacy of vitamin D and vitamin D-calcium fortified dough on glycemic, metabolic, inflammatory, immunity and oxidative stress markers in type 2 diabetes.

Protocol summary

Summary

The aim of this study is to evaluate the possible effects of daily intake of yogurt drink fortified with vitamin D alone or with vitamin D + calcium on some selected glycemic, metabolic, inflammatory and oxidative stress markers in patients with type 2 diabetes (T2DM). To do this, 90 diabetic patients will be selected. Patients who are receiving vitamin D, calcium or omega-3 supplements within the last three months will be excluded. Patients will be assigned randomly to one of the three intervention groups. 1. Plain yogurt drink 2. Vitamin D-fortified yogurt drink 3. Vitamin D-calcium fortified yogurt drink. Each patient will consume 2 servings of yogurt drink every day for 3 months with lunch and dinner. At the first and last visits, dietary and laboratory assessments will be performed for all patients. Primary outcomes are improvement in glycemic, inflammatory and immunity markers and secondary outcome is prevention of long-term diabetic complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810163006N1**
Registration date: **2010-02-26, 1388/12/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-02-26, 1388/12/07

Registrant information

Name

Tirang Reza Neyestani

Name of organization / entity

National nutrition and food technology research institute

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sciences & Health Services

Expected recruitment start date

2009-09-23, 1388/07/01

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

Comparison of efficacy of vitamin D and vitamin D-calcium fortified dough on glycemic, metabolic, inflammatory, immunity and oxidative stress markers in type 2 diabetes.

Public title

Fortified dough and diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age: 30 to 50 years, Fasting blood

glucose ≥ 126 mg/dl. Exclusion criteria: Receiving vitamin D or calcium or omega-3 supplements within the last three months, On any medication which could potentially influence vitamin D metabolism (notably estrogens, and calcitonin) within the last three months, Any other concomitant disease such as renal, hepatic, and other endocrinological disorders, and malignancies, which could influence vitamin D metabolism. Receiving insulin or any change in the type and/or dose of the current hypoglycemic medications

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sci

Street address
West Arghavan St., Farahzadi Blvd., Shahrak Qods,

City
Tehran

Postal code
1981619573

Approval date
2010-01-05, 1388/10/15

Ethics committee reference number
034356

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E 11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
improvement of Vitamin D status

Timepoint
baseline and 3 month after intervention

Method of measurement
serum level of 25OHD

Secondary outcomes

1

Description
improvement of inflammation and immunity markers

Timepoint
Baseline and 3 month after intervention

Method of measurement
serum CRP, IL-6, IgM, IgG, MPO and IL-1β، IFN-γ و TNF-α concentrations in PBMCs culture medium

2

Description
improvement of oxidate stress markers

Timepoint
baseline and 3 month after intervention

Method of measurement
total anti-oxidant capacity [TAC], carbonyl protein, MDA

3

Description
improvement of bone markers

Timepoint
baseline and 3 month after intervention

Method of measurement
serum calcium, phosphor, magnesium, PTH, osteocalcin and osteopontin

Intervention groups

1

Description
interventiona group 1: fortified doogh with 500 IU cholecalciferol per 250 mL

Category
Treatment - Other

2

Description
control group: plain doogh

Category

empty

3

Description
interventional group 2: fortified doogh with 500IU cholecalciferol and 250mg calcium per 250 mL
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
National nutrition and food technology research institute
Full name of responsible person
Dr Neyestani
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West Arghavan St., Farahzadi Blvd., Shahrak Qods,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sci
Full name of responsible person
Dr Mohammad Hossein Azizi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sci
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

Person responsible for general inquiries

Contact
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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