

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Country

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 \geq 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-1 β , IFN- γ , 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

Street address

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

Street address

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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

Name of organization / entity

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

Full name of responsible person

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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*