

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of vitamin D supplementation on the glycaemic status and body fat mass in prediabetic adults: a randomized placebo- controlled trial

Protocol summary

Summary

Objectives: to examine the effect of vitamin D supplementation on glycaemic control and percentage of body fat mass in prediabetic individuals. Design: a single blind, randomized placebo- controlled trial. Sample size was 120 prediabetic adults. Setting and conduct: the subjects using stratified block randomization according to percentage of body fat mass randomly assigned in intervention group (1000 IU/daily vitamin D) or placebo group (placebo tablet) for 3 months. Participants: Participants were adults aged 18-70 years old with prediabetes. exclusion criteria including: type 1 or type 2 diabetes, kidney diseases, sarcoidosis, cancers, hyperparathyroidism, heart diseases, liver diseases, pregnant and breastfeeding, hypercalcaemia, inflammatory bowel disease, cystic fibrosis, gastric bypass surgery, cholecystectomy, and patients who changed their lifestyle and dietary habits during the intervention period. Fasting blood glucose (FBS), Glycated hemoglobin (HbA1c), homeostasis model assessment of insulin resistance (HOMA-IR), serum 25(OH)D levels, and percentage fat mass (FM) were assessed before and after the intervention in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090529508N3**
Registration date: **2016-10-10, 1395/07/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-10, 1395/07/19

Registrant information

Name

Rasoul Zarrin

Name of organization / entity

Urmia University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2015-02-09, 1393/11/20

Expected recruitment end date

2015-06-13, 1394/03/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on the glycaemic status and body fat mass in prediabetic adults: a randomized placebo- controlled trial

Public title

Effect of vitamin D supplementation on the glycaemic status and body fat mass in prediabetic adults: a randomized placebo- controlled trial

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: prediabetic adults; vitamin D Insufficient; 30-70 age group Exclusion criteria: any

diseases which may affect vitamin D metabolism and status or blood glucose control; such as type 1 or type 2 diabetes; kidney diseases; sarcoidosis; cancers; hyperparathyroidism; heart diseases; liver diseases; pregnant and lactating women; poly cystic ovarian syndrome; hypercalcemia; inflammatory bowel disease; cystic fibrosis; gastric bypass surgery; cholecystectomy; serious pulmonary diseases; patients took anti-convulsants; digoxin; contraceptives; orlistat and vitamin D supplements within the last three months; smoking and drinking alcohol; patients who changed their lifestyle and dietary habits during the intervention period; having the threshold serum 25(OH)D of either D3 < 10 nmol/ml or > 150 nmol/ml; patients without informed consent and those who were taking less than 90% of the supplements given to take during the study.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee, Urmia University of Medical Sciences

Street address

Urmia university of Medical Sciences, Urmia

City

Urmia

Postal code**Approval date**

2014-12-30, 1393/10/09

Ethics committee reference number

umsu.rec.1393.212

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

Other disorders of intestinal carbohydrate absorption

ICD-10 code

E74.3

ICD-10 code description

Glucose-galactose malabsorption

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

fasting blood sugar (FBS)

Timepoint

before intervention, 3 months after intervention

Method of measurement

mg/dl

2**Description**

Glycated hemoglobin (HbA1c)

Timepoint

before intervention, 3 months after intervention

Method of measurement

%, Gama

3**Description**

Serum insulin

Timepoint

before intervention, 3 months after intervention

Method of measurement

mg/dl

4**Description**

Percentage body fat mass

Timepoint

before intervention, 3 months after intervention

Method of measurement

%, kaliper

5**Description**

Serum 25(OH)D

Timepoint

before intervention, 3 months after intervention

Method of measurement

ng/ml

6**Description**

homeostasis model assessment of insulin resistance (HOMA-IR)

Timepoint

before intervention, 3 months after intervention

Method of measurement

FBS*Insulin

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

Daily sun exposure

Timepoint

before intervention, 3 months after intervention

Method of measurement

hour

2**Description**

Waist Circumference

Timepoint

before intervention, 3 months after intervention

Method of measurement

cm

3**Description**

Body Mass Index (BMI)

Timepoint

before intervention, 3 months after intervention

Method of measurementkg/m²**Intervention groups****1****Description**

Control group: placebo tablet for 3 months

Category

N/A

2**Description**

Intervention group: 1000 IU/daily vitamin D for 3 months

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam KHomeini hospital

Full name of responsible person

Dr. Rasoul Zarrin

Street address

Emam KHomeini hospital, Ershad Street, Modarres Ave, Urmia, Iran

City

Urmia

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Urmia University of Medical sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences, Jahad Street, Resalat Ave, Urmia

City

Urmia

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, Urmia University of Medical sciences

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**

Urmia University of Medical Sciences

Full name of responsible person

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Assistant Professor of Nutrition

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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