

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 measurement
kg/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
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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
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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