Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of vitamin D supplementation on insulin resistance and glycemic control in patients with diabetes type 2

Protocol summary

Summary

This double blind, randomized, placebo-controlled study will be performed with the aim of whether vitamin D supplementation can effect on insulin resistance and glycemic control in type 2 diabetic patients. 120 patients with diabetes type 2 according to these inclusion critera: ADA criteria 2011 and under treatment with oral hypoglycemic agents HbA1C<8.5%, patients with 21-60 of age, BMI>20 and exclusion critera of end stage diseases of organs such as ESRD,chronic liver disease, GFR<30ml/min,hypercalcemia and kidney stones, known primary hyperparathyroidism,consumption of vitamin D supplement over 400 IU within 2 months prior to intervention will be selected . initial testing of fasting blood glucose, 2 hours postprandial glucose, calcium, phosphorus, BUN, creatinine, HbA1C, 25 (OH) D and fasting serum insulin levels will be measured. 60 patients in the intervention group receivedVitamin D 50000 Units and 60 patients received placebo every two weeks. After 12 weeks (3 months) of intervention, fasting blood glucose, 2 hpp, HbA1C, fasting serum vitamin D levels will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012061110002N1**
Registration date: **2013-03-25, 1392/01/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-03-25, 1392/01/05

Registrant information

Name

Monireh Bazdar

Name of organization / entity

Ahvaz Jondi Shapour University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Ahvaz University of Medical Sciences, DiabetesR esearch Center

Expected recruitment start date

2013-03-05, 1391/12/15

Expected recruitment end date

2013-05-10, 1392/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on insulin resistance and glycemic control in patients with diabetes type 2

Public title

Effect of vitamin D supplementation on diabetes type 2

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion critera : 1) patients with diabetes type 2 according to ADA criteria 2011 and under treatment with oral hypoglycemic agents, 2) HbA1C ≤ 8.5%, 3) patients with 21-60 of age, 4) BMI>20 exclusion criteria : 1) end stage diseases of organs such as ESRD,chronic liver disease 2)GFR≤30ml/min, 3) hypercalcemia and kidney

stones,4) known primary hyperparathyroidism,5) heart diseases included ischemic heart disease, heart failure,cardiomyopathy,6) sarcoidosis,7) TB ,8) cancer,9) history of IBD ,10) pregnancy,11) SBP/SDP≥175/104 mmHg ,12) consumption of vitamin D supplement over 400 IU within 2 months prior to intervention

Age
From **21 years** old to **60 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)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research and Technology Deputy, Research Ethics Committee

Street address
Ahvaz University City, Department of Research and Technology, Ahvaz Jundishapur University of Medical Sciences and Health Services

City
Ahvaz

Postal code
61357-15794

Approval date
2013-02-17, 1391/11/29

Ethics committee reference number
ETH-390

Health conditions studied

1

Description of health condition studied
Diabetes type 2

ICD-10 code
E-11

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

Primary outcomes

1

Description
Insulin resistance and glycemic control (glucose*insulin/405)

Timepoint
just before and after 3 months of intervention

Method of measurement
alisun 3000 measure system

2

Description
HOMA-Beta

Timepoint
just before after 3 months of intervention

Method of measurement
glucose* insulin /405

3

Description
Hb A1C

Timepoint
just before after 3 months of intervention

Method of measurement
high performance liquid chromatography method using G8 TOSO Ssystem

4

Description
HOMA - IR

Timepoint
just before and 3 months after intervension

Method of measurement
insulin* 360 / glucose -63 %

Secondary outcomes

1

Description
Determination and comparison of the distribution of vitamin D (25 (OH) D) levels before and after treatment in both intervention and control groups

Timepoint
just before and after 3 months of intervention

Method of measurement
Chemiluminescence method using liusun system

Intervention groups

1

Description
placebo group will recieve placebo capsul made of hard

jellatinous material as the same method as intervention group.

Category

Treatment - Drugs

2

Description

Intervention group will recieve 50000 IU vitamin D3 every 2 weeks for 3 months orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Golestan Hospial in Ahvaz City

Full name of responsible person

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Teputy, Diabetes Research Center

Full name of responsible person

Dr.Mohammad Reza Abbass Pour; Director of Research Affairs

Street address

Ahwaz City University, Department of Research and Technology, Ahvaz Jundishapur University of Medical Sciences and Health Services

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research and Technology Teputy, Diabetes Research Center

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

Diabetes Research Center

Full name of responsible person

Dr.Homeyra Rashidi

Position

Research Assistant Diabetes Research Center

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Diabetes Research Center

Full name of responsible person

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Position

Endocrinologist, Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Monireh Bazdar

Position

Resident of Internal Medicine, MD

Other areas of specialty/work

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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