

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Vitamin D Supplement in comparison whit placebo on insulin resistance and prevention of Diabetes Mellitus Type 2 in Patients with Pre-diabetes

Protocol summary

Summary

The purpose of study is to evaluate effect of Vitamin D Supplement on insulin resistance and the incidence of Type 2 Diabetes Mellitus in patients with prediabetes (IFG or IGT) and vitamin-D deficiency. This is a triple blinded placebo controlled clinical trial (researcher, patient, analyzer). The study population consists of all adult patients with pre-diabetes presenting to endocrinology clinic. Inclusion criteria include 18 years of age, pre diabetes, and vitamin-D deficiency. Exclusion criteria include patients with overt diabetes or other medical conditions that interfere with glucose metabolism, and chronic use of medications that interfere with glucose metabolism. 80 subjects will enroll in each group. Past medical history will be obtained and height, weight, waist circumference will be measured and Body Mass Index calculated for all participants. A blood sample will be drawn and FPG and serum insulin will be measured. Then 75-gr OGTT will be done. For evaluation of insulin resistance HOMA-IR index will be used. In vitamin D group, fifteen 50,000 IU Vitamin-D pearls will be administered weekly for 3 months then 1 pearl monthly. In the control group, placebo pearls will be administered with similar schedule. At the end of month 3 and 6 weight and waist circumference will be measured. The two groups will be compared regarding FPG, serum vitamin D, insulin resistance and OGTT results.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050413223N1**

Registration date: **2015-06-16, 1394/03/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-16, 1394/03/26

Registrant information

Name

Mahtab Niroomand

Name of organization / entity

Shahid Beheshty University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8826 2390

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m.niroomand@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Science

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Vitamin D Supplement in comparison whit placebo on insulin resistance and prevention of Diabetes Mellitus Type 2 in Patients with Pre-diabetes

Public title

The effect of Vitamin D Supplement on Insulin Resistance

and Prevention of Diabetes Mellitus Type 2 in Patients with Pre-diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: adult patients who are over 18 years old; pre-diabetes (IFG or IGT) and vitamin-D deficiency; obtained informed consent. Exclusion criteria: overt Diabetes Mellitus; condition which interfere with glucose metabolism (malignancy, CRF, , inflammatory disease...); diseases like thyroid disease or mal-absorption; take medication that interfere with glucose metabolism (Steroids, HRT, Diuretics).

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences, Ethics committee

Street address

Next to Ayatollah Taleghani Hospital, Velenjak

City

Tehran

Postal code

1985717443

Approval date

2013-02-24, 1391/12/06

Ethics committee reference number

131th Ethics committee

Health conditions studied

1

Description of health condition studied

pre-diabetes (IFG or IGT)

ICD-10 code

E11

ICD-10 code description

Impaired glucose tolerance R73.0 Diabetes: chemical latent Impaired glucose tolerance Prediabetes

Primary outcomes

1

Description

Diabetes(75gr-OGTT):Assessment of fasting plasma glucose after at least 8-hours fasting then 2 hours after administration of 75 gram glucose, Insulin resistance evaluated by calculating HOMA-IR

Timepoint

Before intervention, 3 and 6 months after intervention

Method of measurement

Fasting plasma sample for evaluation of FPG and Serum insulin, Oral glucose tolerance test(OGTT) with 75gr glucose

Secondary outcomes

1

Description

height, weight, BMI, waist circumference

Timepoint

Every 3 months

Method of measurement

height (cm), weight (kg), BMI (kg/squared meters), waist circumference(cm)

Intervention groups

1

Description

In Case Group/Vitamin D Group :Vitamin D will be administered as PO (15 Vitamin D pearls). In the first 3 months, the subjects will take one pearl (50,000 IU) every week. Then three pearls will be used for 3 months (one pearl monthly).

Category

Treatment - Drugs

2

Description

In the Control Group, placebo pearls (using paraffin and prepared by Zahravi Pharmaceutical Company) with the same size, shape, and color as the original ones will be administered as PO (15 Vitamin D pearls). In the first 3 months, the subjects will take one pearl every week. Then three pearls will be used for 3 months (one pearl monthly).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohda-Tajrish Hospital

Full name of responsible person

Mahtab Niroumand, Endocrinologist, Assistant professor

Street address

Shahrdari stt, Tajrish squire

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Gudarzi H.MD. Vice dean for research

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Next to Ayatollah Taleghani Hospita

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahtab Niroumand

Position

Endocrinologist/Assistant Professor

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Full name of responsible person

Mahtab Niroumand

Position

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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