

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of vitamin D supplementation on serum vitamin D levels and markers of metabolic and inflammatory in women with gestational diabetes

Protocol summary

Summary

In this study, patients who suffered from gestational diabetes in the academic outpatient clinic at Alzahra Hospital of the Tabriz University of Medical Sciences, will be assessed in order to determine the Effects of vitamin D supplementation on serum vitamin D levels, markers of metabolic and inflammation in women with gestational diabetes. Inclusion criteria consists of: gestational diabetes; age between 15 and 45 years old and gestational age 24-28 weeks and exclusion criteria are: thyroid and parathyroid disorders, kidney disease, heart disease, hypertension, smoking and usage of nutritional supplements containing vitamin D in the past 6 months. 45 subjects will be divided into two groups randomly (taking the vitamin D supplement and control). Participants will receive 4 oral treatments consisting of 50000 IU of vitamin D3 (D-Vit 50 000; Zahravi Pharm Co, Tabriz, Iran), or a placebo (Zahravi Pharm Co), 1 every 2 weeks for 8 weeks. Every 2 weeks, vitamin D and placebo will be delivered to people. For each Patient questionnaire will be filled and general characteristics, anthropometric measurements (height and weight to calculate BMI) will be assessed. For each patient, 24-h recall questionnaire will be filled in order to assessment of energy, macronutrient and vitamin D intake for 3 days a week (2 working days and 1 holiday). These questionnaires will be completed at baseline and 8th week of the study. Ten ml blood sample from each patient will be taken after 12-14 hours fasting at the beginning and end of the intervention, and serum 25 OH vitamin D, fasting blood glucose levels, HbA1c, fasting serum insulin, insulin resistance, serum lipids and hs-CRP in both groups before and after the intervention will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306253140N11**
Registration date: **2013-07-05, 1392/04/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-05, 1392/04/14

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1435 7580

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-10-22, 1392/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of vitamin D supplementation on serum vitamin D levels and markers of metabolic and inflammatory in women with gestational diabetes

Public title
Effect of vitamin D supplementation in the treatment of patients with gestational diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: gestational diabetes; age between 15 and 45 years old and gestational age 24-28 weeks.
Exclusion criteria: thyroid and parathyroid disorders, kidney disease, heart disease, hypertension, smoking and usage of nutritional supplements containing vitamin D in the past 6 months.

Age
From **15 years** old to **45 years** old

Gender
Female

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)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Golbad Street, Tabriz University of Medical Sciences
Golbad Street, Tabriz University of Medical Sciences

City
Tabriz

Postal code

Approval date

2013-05-20, 1392/02/30

Ethics committee reference number
9249

Health conditions studied

1

Description of health condition studied
Gestational diabetes mellitus

ICD-10 code
O24.9

ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
Serum 25 (OH) vitamin D3

Timepoint
Baseline and after 8 weeks of intervention

Method of measurement
chemiluminescence immunoassay system

2

Description
Fasting blood glucose

Timepoint
Baseline and after 8 weeks of intervention

Method of measurement
Enzymatic colorimetric

3

Description
serum Fasting insulin

Timepoint
Baseline and after 8 weeks of intervention

Method of measurement
chemiluminescence immunoassay system

4

Description
HbA1C (Glycosilated hemoglobin)

Timepoint
Baseline and after 8 weeks of intervention

Method of measurement
Chromatography

5

Description
Insulin resistance

Timepoint
Baseline and after 8 weeks of intervention

Method of measurement
HOMA-IR calculation

6

Description

Total cholesterol

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

Enzymatic methods

7

Description

Triglycerides

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

Enzymatic methods

8

Description

HDL-Cholesterol

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

Enzymatic methods

9

Description

high sensitivity-C reactive protein

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

Nephelometry

10

Description

LDL-Cholesterol,

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

Freidwald's formula: $LDL-C = TC - HDL-C - (TG/5)$

Secondary outcomes

1

Description

Energy and macronutrients intake and vitamin D intake

Timepoint

before and after 8 weeks intervention

Method of measurement

24-h recall Questionnaire

2

Description

body mass index

Timepoint

before and after 8 weeks intervention

Method of measurement

weight(Kg)/Square Height

Intervention groups

1

Description

Intervention group will receive 4 oral vitamin D supplement capsules consisting of 50000 IU of vitamin D3) 1 every 2 weeks for 8 weeks. Vitamin D supplements will be purchased from the Zahravi Pharm Co. All the patients will receive the supplement on every two weeks base and will be monitored for consumption continuation and any possible adverse effects by telephone interviews

Category

Treatment - Drugs

2

Description

The control group received 4 oral placebo (containing paraffin) 1 every 2 weeks for 8 weeks. Vitamin D supplements will be purchased from the Zahravi Pharm Co. All the patients will receive the supplement on every two weeks base and will be monitored for consumption continuation and any possible adverse effects by telephone interviews

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Academic outpatient clinic at Alzahra Hospital of the Tabriz University of Medical Sciences.

Full name of responsible person

Roya Yazdchi

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Seyed Kazem Shakouri

Street address

Golbad Street

City

Tabriz

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, Tabriz 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**

Tabriz University of Medical Sciences, Faculty of Health and Nutrition

Full name of responsible person

doctor Bahram Poor Gaseme Gargari

Position

PHD in Nutrition Sciences

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Golgasht Street, St. Attar, School of Public Health Nutrition

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Full name of responsible person

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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