

# 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

##### Email address

pourghassemb@tbzmed.ac.ir

##### 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

**Other areas of specialty/work****Street address**

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

**City**

Tabriz

**Postal code****Phone**

+98 41 1335 7580

**Fax****Email**

bahrampg@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

doctor Bahram Poor gaseme Gargari

**Position**

PHD in Nutrition Sciences

**Other areas of specialty/work****Street address**

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

**City**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Roya Yazdchi

**Position**

MSc student in nutrition sciences

**Other areas of specialty/work****Street address**

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**City**

Tabriz

**Postal code****Phone**

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**Fax****Email**

Roya\_yazdchi@yahoo.com

**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*