

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Vitamin D supplementation on blood pressure, bone parameters, lipid profile, liver enzymes, glycemic and hematopoietic indices in pregnant women with vitamin D deficiency

#### Protocol summary

##### Summary

To determine the effect of Vitamin D supplementation on blood pressure, bone parameters, lipid profile, liver enzymes, glycemic and hematopoietic indices in pregnant women with vitamin D deficiency. It is a clinical trial study (before and after). The study population are 30 pregnant women with vitamin D deficiency. In the first stage of Intervention: to give a 50000 Units of Vitamin D weekly for 12 weeks. In the second stage of intervention: to give a 50000 Units of Vitamin D monthly for 3 months. In three steps, before and after the first stage of Intervention and second stage of intervention blood pressure systolic and diastolic serum 25OHD, Calcium, Phosphorus, Magnesium, PTH, Alkaline phosphatase, Aspartate aminotransferase, Alanine aminotransferase, low density Lipoprotein, high density Lipoprotein cholesterol, triglycerides, FBS, glycosylated hemoglobin, fasting insulin, insulin resistance, ferritin, transferrin saturation, iron, TIBC, RBC, MCH, MCHC, HCT, Hb MCV, will be measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014091619162N5**

Registration date: **2015-03-26, 1394/01/06**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-03-26, 1394/01/06

##### Registrant information

##### Name

Maryam Taghdir

##### Name of organization / entity

Baqiyatallah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8804 0153

##### Email address

mtaghdir@bums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Baqiyatallah University of Medical Science

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### 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 supplementation on blood pressure, bone parameters, lipid profile, liver enzymes, glycemic and hematopoietic indices in pregnant women with vitamin D deficiency

##### Public title

The effect of Vitamin D3 supplementation on blood pressure, bone parameters, lipid profile, liver enzymes, glycemic and hematopoietic indices in pregnant women with Vitamin D deficiency

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: women between 14-12 weeks of

pregnancy; the level of serum 25OHD<20ng /ml; with a body mass index less than 30 Kg/m<sup>2</sup>; age less than 35 years; normal blood pressure; not having any systemic disease such as Cardiovascular disease; renal disease, diabetes, heart disease, liver disease; In the past 6 months did not receive vitamin D supplements; not to have calcium deficiency; not smoking; and alcohol consumption; Not taking anticonvulsant drugs or any other drugs; singleton pregnancy; first pregnancy or 3 years spacing between two pregnancy. Exclusion criteria: presence of any systemic disease.

#### Age

From **18 years** old to **35 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Baqiyatallah University of Medical Sciences

##### Street address

Baqiyatallah University of Medical Sciences, South Sheikh Bahaei street, Mollasadra Avenue, Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2014-11-22, 1393/09/01

#### Ethics committee reference number

5904

## Health conditions studied

### 1

#### Description of health condition studied

Vitamin D Deficiency

#### ICD-10 code

E55.9

#### ICD-10 code description

Vitamin D Deficiency, unspecified

## Primary outcomes

### 1

#### Description

Magnesium

#### Timepoint

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

#### Method of measurement

In milligrams per deciliter and by autoanalyzer

### 2

#### Description

Phosphor

#### Timepoint

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

#### Method of measurement

In milligrams per deciliter and by autoanalyzer

### 3

#### Description

Calcium

#### Timepoint

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

#### Method of measurement

In milligrams per deciliter and by autoanalyzer

### 4

#### Description

PTH

#### Timepoint

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

#### Method of measurement

In milligrams per deciliter and by autoanalyzer

### 5

#### Description

Alkaline Phosphatase

#### Timepoint

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

#### Method of measurement

In milligrams per deciliter and by autoanalyzer

### 6

#### Description

25OHD Serum

#### Timepoint

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are ng / ml using 25OHD ALIZA

**7**

**Description**

Diastolic Blood Pressure

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

In millimeters of mercury sphygmomanometer

**8**

**Description**

Systole Blood Pressure

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

In millimeters of mercury sphygmomanometer

**9**

**Description**

FBS

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are mg / dl using autoanalyzer

**10**

**Description**

Insulin

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are  $\mu$ U / ml using insulin kits

**11**

**Description**

Insulin Resistance

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Using the index, HOMA-ir

**12**

**Description**

HbA1c

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are % using HbA1c kits

**13**

**Description**

Ferritin

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are ng / ml ferritin kits

**14**

**Description**

Transferrin Saturation

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are % using serum Iron/TIBC x 100

**15**

**Description**

Serum Iron

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are  $\mu$ g / dl using iron kits

**16**

**Description**

TIBC

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are  $\mu$ g / dl using TIBC kits

**17**

**Description**

RBC

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are  $\mu$ L using cell counter

**18**

**Description**

Hb

**Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

**Method of measurement**

Units are g/dl using cell counter

## **19**

### **Description**

HCT

### **Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

### **Method of measurement**

Units are % using cell counter

## **20**

### **Description**

MCV

### **Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

### **Method of measurement**

Units are fL using cell counter

## **21**

### **Description**

MCH

### **Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

### **Method of measurement**

Units are Pg using cell counter

## **22**

### **Description**

MCHC

### **Timepoint**

Three times: 1) before supplementation 2)After weekly supplementation for 12 weeks 3) Delivery time

### **Method of measurement**

Units are g/dl using cell counter

## **23**

### **Description**

Cholesterol

### **Timepoint**

Three times:1)Befor of supplementation 2)after weekly supplementation for 12 week3) delivery time

### **Method of measurement**

In mg/dl and by autoanalyzer

## **24**

### **Description**

Triglycerides

### **Timepoint**

Three times:1)Befor of supplementation 2)after weekly supplementation for 12 week3) delivery time

### **Method of measurement**

In mg/dl and by autoanalyzer

## **25**

### **Description**

Low Density Lipoprotein

## **Timepoint**

Three times:1)Befor of supplementation 2)after weekly supplementation for 12 week3) delivery time

### **Method of measurement**

In mg/dl and by auto analyzer

## **26**

### **Description**

High Density Lipoprotein

### **Timepoint**

Three times:1)Befor of supplementation 2)after weekly supplementation for 12 week3) delivery time

### **Method of measurement**

In mg/dl and by autoanalyzer

## **27**

### **Description**

ALanin Amino Teransferase

### **Timepoint**

Three times:1)Befor of supplementation 2)after weekly supplementation for 12 week3) delivery time

### **Method of measurement**

in Unit per liter and by Autoanalyzer

## **28**

### **Description**

Aspartat Amino Teransferase

### **Timepoint**

Three times:1)Befor of supplementation 2)after weekly supplementation for 12 week3) delivery time

### **Method of measurement**

In unit per liter and by autoanalyzer

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

In the first stage of Intervention: to give a 50000 Units of Vitamin D weekly for 12 weeks. In the second stage of intervention:to give a 50000 Units of Vitamin D monthly for 3 months.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Gynecology & Obstetrics Clinic of Baqiyatallah Hospital

##### **Full name of responsible person**

Dr.Seyedeh Razieh Hashemi

##### **Street address**

Gynecology & Obstetrics Clinic, Baghiatallah Hospital,

Mollasadra Avenue, Tehran, Iran

**City**

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Maryam Taghdir

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**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Baqiyatallah 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**

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**Full name of responsible person**

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**Position**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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Instructor

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## Person responsible for updating data

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**Other areas of specialty/work**

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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*