Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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)

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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/m2; 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 µIU / 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 µg / 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 µg / 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 µL 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 Autoanalyser

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
Gyncology & Obstetrics Clinic of Baqiyatallah Hospital
Full name of responsible person
Dr.Seyedeh Razieh Hashemi
Street address
Gyncology & Obstetrics Clinic, Baghiatallah Hospital,

Mollasadra Avenue, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Maryam Taghdir

Street address

School of Public Health, Baqiyatallah University of Medical Sciences, Barazil street, South Sheikh Bahae street, Mollasadrai Avenue, Tehran, Iran

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

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Tahereh Babashamsi, Saeideh Nahani, Simindokht Esmaeilzadeh

Position

MSc Student

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

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Position

Instructor

Other areas of specialty/work

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Person responsible for updating data

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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