

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparing the effect of Therapeutic Doses of 200 and 50000 Units of Vitamin D on Serum 25(OH)D Levels in Pregnant Women Referred to Shahid Sayyad Shirazi Hospital of Gorgan between 2013-14

Protocol summary

Summary

Objectives: This study was designed to compare the effects of therapeutic doses of 200 and 50,000 IU of vitamin D on 25 (OH) D serum levels in pregnant women. **Design:** In this non-randomized clinical trial, study samples will be selected among pregnant women at gestational age of 12-16 weeks admitted to Sayyad Shirazi Hospital in Gorgan between 2013-14. **Setting and Conduct:** Eligible women will be enrolled after obtaining written informed consent and divided into two groups (A, B) and randomly will be placed 45 pregnant women in each group. First, a questionnaire containing demographic characteristics for pregnant mothers will be completed. **Inclusion criteria:** gestational age 12-16 weeks based on first trimester ultrasound or accurate LMP; nulliparity; singleton pregnancy; vitamin D deficiency. **Exclusion criteria:** incomplete treatment of supplements or impossible follow-up; a history of high-risk pregnancy; a history of parathyroid disease; hypocalcemia or hypercalcemia; underlying disease such as liver disease, renal disease; hypertension and malabsorption disorders; diabetes based on routine tests done during pregnancy. **Intervention:** blood samples will be taken from pregnant women participating in the study to determine serum levels of 25 (OH) D. Then, group A will be treated with 200 IU of vitamin D supplements orally for 8 weeks and the women in group B will be treated with 50,000 IU of vitamin D supplements orally weekly for 8 weeks. **Main outcome measures:** Pregnant women will be followed until delivery and on term delivery will be evaluated in terms of maternal outcomes such as gestational diabetes, preeclampsia and preterm labor and blood samples in order to reassess the serum levels of D (OH) 25 will be taken. The samples are also assessed to check for hypervitaminosis and safety of treatment with different doses of vitamin D. Collected data will be analyzed by SPSS-21 statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121120276N1**
Registration date: **2016-09-24, 1395/07/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-24, 1395/07/03

Registrant information

Name

Malihe Azadeh Rah

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 3223 2269

Email address

m.azadehrah@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Gorgan Congenital Malformations Research Center of Golestan University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-10-28, 1393/08/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Therapeutic Doses of 200 and 50000 Units of Vitamin D on Serum 25(OH)D Levels in Pregnant Women Referred to Shahid Sayyad Shirazi Hospital of Gorgan between 2013-14

Public title

Comparing the effect of Therapeutic Doses of 200 and 50000 Units of Vitamin D on Serum 25(OH)D Levels in Pregnant Women Referred to Shahid Sayyad Shirazi Hospital of Gorgan between 2013-14

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria included gestational age 12-16 weeks based on first trimester ultrasound or accurate LMP; nulliparity; singleton pregnancy; vitamin D deficiency. Exclusion criteria included incomplete treatment of supplements or impossible follow-up; a history of high-risk pregnancy; a history of parathyroid disease; hypocalcemia or hypercalcemia; underlying disease such as liver disease, renal disease; hypertension and malabsorption disorders (based on medical history or personal statements); diabetes (based on routine tests done during pregnancy).

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Golestan University of Medical Sciences

Street address

Medical Faculty, Golestan University of Medical Sciences, Shast kola, Hirakan avenue, Gorgan, Iran

City

Gorgan

Postal code

49157-44545

Approval date

2014-04-21, 1393/02/01

Ethics committee reference number

1723059307201

Health conditions studied**1****Description of health condition studied**

Vitamin D Deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D Deficiency

Primary outcomes**1****Description**

Efficacy of different doses of vitamin D supplements and treatment of vitamin D deficiency in pregnant women

Timepoint

20 weeks after intervention

Method of measurement

Measurement of serum levels of 25 (OH) D in ng/dl

Secondary outcomes**1****Description**

Prevention of maternal and neonatal complications of pregnancy

Timepoint

20 weeks after intervention

Method of measurement

Evaluation on term delivery in terms of complications

2**Description**

Safety of treatment with vitamin D supplement

Timepoint

20 weeks after intervention

Method of measurement

Evaluation on term delivery in terms of hypervitaminosis and drug side effects

Intervention groups

1

Description

Group A will be treated with 200 IU of vitamin D supplements orally for 8 weeks.

Category

Treatment - Drugs

2

Description

The women in group B will be treated with 50,000 IU of vitamin D supplements orally weekly for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Hospital

Full name of responsible person

Dr.Elham Mobasheri

Street address

Sayyad Shirazi Hospital, Sayyad Shirazi avenue, Gorgan, Iran

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan Congenital malformations research center, Golestan University of Medical Sciences,Gorgan, Ira

Full name of responsible person

Dr.Mohammad Jafar Golaipour

Street address

Gorgan Congenital malformations research center, Sayyad Shirazi hospital, Golestan University of Medical Sciences,Gorgan, Iran

City

Gorgan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan Congenital malformations research center, Golestan University of Medical Sciences,Gorgan, Ira

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

Golestan University of Medical Sciences

Full name of responsible person

Dr. Malihe Azadehrah

Position

Resident of Gyneacology

Other areas of specialty/work

Street address

Sayyad Shirazi Hospital, Sayyad Shirazi avenue, Gorgan, Iran

City

Gorgan

Postal code

49166-56789

Phone

+98 17 3226 1150

Fax

+98 17 3224 4660

Email

m.azadehrah@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Dr. Elham Mobasheri

Position

Gyneacologist/Associate Professor

Other areas of specialty/work

Street address

Sayyad Shirazi Hospital, Sayyad Shirazi avenue, Gorgan, Iran

City

Gorgan

Postal code

49166-56789

Phone

+98 17 3226 1150

Fax

+98 17 3224 4660

Email

elmobasheri@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Dr. Malihe Azadehrah

Position

Resident of Gyneacology

Other areas of specialty/work

Street address

Sayyad Shirazi Hospital, Sayyad Shirazi avenue,
Gorgan, Iran

City

Gorgan

Postal code

49166-56789

Phone

+98 17 3226 1150

Fax

+98 17 3224 4660

Email

m.azadehrah@gmail.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