

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of two therapeutic regimens Vitamin D3 deficiency in the first trimester of pregnancy on the level of vitamin D3 in the second trimester of pregnancy

#### Protocol summary

##### Study aim

Obtaining an overview of the effects of various therapies on vitamin D deficiency in pregnancy and choosing a suitable method for the treatment of pregnant women

##### Design

Pregnant mothers who referred to the gynecologic clinic were randomly assigned to two oral treatment groups A (vitamin D3 in the form of a Perl 50,000 units once a week for up to 10 weeks) and group B (oral treatment in the form of a pill of vitamins D3 was divided into 1000 units per day for up to 10 weeks), and only the laboratory results were blind to hide the intervention group.

##### Settings and conduct

A study was conducted on mothers who vitamin D deficiency and they were referred to a gynecology and obstetric clinic for prenatal care. They were individually non-randomly divided into two groups of oral vitamin D treatment groups of 1000 and 50,000 units. Serum levels were blinded in the laboratory to hide the type of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria, serum Vitamin D level is less than 30 ng/ml . Exclusion criteria, the occurrence of any complication related to treatment ( nausea, vomiting, fatigue, weakness, headache, frequent urination, dry mouth )

##### Intervention groups

The intervention group was a pregnant mothers with vitamin D deficiency who received a dose of 50,000 units of vitamin D3 once a week. Control group was pregnant women with vitamin D deficiency who received a dose of 1000 unit per day. Both groups received these doses from week 14 of pregnancy to ten weeks.

##### Main outcome variables

Study of Serum levels of vitamin D3 in both groups with dose of 1000 and 50000 units of vitamin D3 before and

after treatment .

#### General information

##### Reason for update

##### Acronym

VDD

##### IRCT registration information

IRCT registration number: **IRCT2016040527227N1**

Registration date: **2017-07-10, 1396/04/19**

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

Last update: **2018-05-05, 1397/02/15**

Update count: **2**

##### Registration date

2017-07-10, 1396/04/19

##### Registrant information

##### Name

Dr. Sedigheh Hantoshzadeh

##### Name of organization / entity

Tarbiat Modares University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6690 1515

##### Email address

farahnaz.rostami@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tarbiat Modares of Medical Science

##### Expected recruitment start date

2016-06-19, 1395/03/30

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### Actual recruitment start date

2016-07-20, 1395/04/30  
**Actual recruitment end date**  
2017-07-21, 1396/04/30  
**Trial completion date**  
empty

**Scientific title**  
Comparison of two therapeutic regimens Vitamin D3 deficiency in the first trimester of pregnancy on the level of vitamin D3 in the second trimester of pregnancy

**Public title**  
Therapeutic regimens for Vitamin D3 deficiency

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Serum Vitamin D level is less than 30 ng / ml Gestational age less than 14 weeks Age 18-42 years Not chronic disease, impaired absorption and metabolism of food Single pregnancy Not receiving any supplement except multivitamins to 400 unite Vitamin D3, folic acid, iron and calcium with 400 units Vitamin D3 Having Iranian nationality  
**Exclusion criteria:**  
Unwillingness to continue participating in the study The occurrence of any complication related to treatment (nausea, vomiting, fatigue, weakness, headache, frequent urination, dry mouth) Do not use the correct medicine People who have special diets, including vegetarian diet, etc.

**Age**  
From **18 years** old to **42 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: **200**  
Actual sample size reached: **222**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Clinical lab ,it was blind. According to the review of serum levels of vitamin D, it did not know what type of treatment they would receive

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tarbiat Modarres University of Medical Science

##### Street address

14115-111, Post box , Tarbiat Modares University, Intersection Al Ahmad Street , Shahid Chamran Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713116

##### Approval date

2016-07-10, 1395/04/20

##### Ethics committee reference number

IR.TMU.REC.1395.368

## Health conditions studied

### 1

#### Description of health condition studied

Vitamine D deficiency

##### ICD-10 code

E55

##### ICD-10 code description

Vitamin D deficiency

## Primary outcomes

### 1

#### Description

Check of the serum levels of vitamin D

#### Timepoint

First Trimester and Second Trimester

#### Method of measurement

Blood Exam

## Secondary outcomes

### 1

#### Description

Delete

#### Timepoint

Delete

#### Method of measurement

Delete

## Intervention groups

### 1

#### Description

Group Therapy A: Oral Treatment of vitamin D perl

50,000 units once a week to 10 weeks

**Category**

Treatment - Drugs

**2**

**Description**

Group Therapy B, Oral Treatment of vitamin D Tablet 1000 unite daily for 10 weeks

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Clinic of Gynecology and Obstetric

**Full name of responsible person**

Farahnaz. rostami

**Street address**

14115-111, Post box, Intersection Al Ahmad Street, Shahid Chamran Highway, Tehran ,Iran

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**Province**

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frostami22@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tarbiat Modares University of Medical Science, Tehran

**Full name of responsible person**

Doctor Yaghub Fatollahi

**Street address**

14115-111, Post box, Intersection Al Ahmad Street, Shahid Chamran Highway , Tehran

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**Email**

fatollahi@modares.ac.ir

**Grant name**

52640/5

**Grant code / Reference number**

1273432

**Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Tarbiat Modares University of Medical Science, Tehran

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tarbiat Modares University of Medical Science

**Full name of responsible person**

Farahnaz Rostami

**Position**

Master / Student

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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farahnaz.rostami@modares.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical

**Full name of responsible person**

Doctor Sedigheh Hantoshzadeh

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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Hantoushzadeh@tums.ac.ir

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

Tarbiat Modares of Medical Science

**Full name of responsible person**

Doctor Lida Moghadambanaem

**Position**

Associate Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Others

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14115-111, Post box, Intersection Al Ahmad street,  
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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

All participants have signed a written consent to participate in this study and all of their information will not be publish elsewhere

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Statistical information data

**When the data will become available and for how long**

Starting the access period from 1398 after printing

**To whom data/document is available**

Researchers working in academic and academic institutions

**Under which criteria data/document could be used**

Qualitative and quantitative data is permitted for various analyzes and the use of documentation is permitted in health surveys.

**From where data/document is obtainable**

1. farahnaz.rostami@modares.ac.ir Phone number 09023104044 Mrs Rostamiand 2.Thesis Departmen, Library of Tarbiat Modares University

**What processes are involved for a request to access data/document**

After receipt of an email or text message from the researcher, within two months, the document or file will be sent.

**Comments**