Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Tretment 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

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 0000

Email

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 Yaghob Fatollahi

Street address

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

City

Tehran

Province

Tehran

Postal code

:1411713116

Phone

+98 21 8288 2009

Email

fatolahi@modares.ac.ir

Grant name

52640/ه

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 Medicai Science

Full name of responsible person

Farahnaz Rostami

Position

Master / Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

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

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 6690 1515

Fax

Email

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

Street address

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

City
Tehran
Province
Tehran
Postal code
3439123900
Phone
+98 21 6690 1515
Fax
Email
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
Street address
14115-111, Post box, Intersection Al Ahmad street, Shahid Chamran highway , Tehran
City
Tehran
Province
Tehran
Postal code
1493675683
Phone
+98 21 8288 3857
Fax
Email
moghaddamb@modares.ac.ir
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