

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of optimal vitamin D dose for treatment of hypovitaminosis D in pregnant women

Protocol summary

Study aim

Due to the adverse effects of vitamin D deficiency on the fetus and mother,

Design

In this study, pregnant women living in Shahroud in the age range of 18 to 45 years and gestational age under 14 weeks with a level of vitamin D below 20 ng / ml are included in the study. The sample size is 55 people and randomly divided into three groups receiving different doses. Vitamin D is divided into which the first group receives vitamin D 1000 daily, the second 2000 daily and the third 4000 daily

Settings and conduct

In this study, pregnant mothers living in Shahroud in the age range of 14 to 45 years and gestational age under 14 weeks referring to the clinic of Bahar Hospital in Shahroud are selected and their vitamin D level is measured with ELISA and vidas kit. Vitamin D levels below 20 ng are included in the study These people are randomly divided into three groups receiving different doses of vitamin D. Vitamin D levels are determined and compared in groups at 28 weeks of gestation

Participants/Inclusion and exclusion criteria

Pregnant mothers living in Shahroud in the age range of 18 to 45 years and with a gestational age of less than 14 weeks,

Intervention groups

Pregnant mothers living in Shahroud in the age range of 18 to 45 years and with a gestational age of less than 14 weeks, are selected and entered the study with vitamin D levels below 20 ng / ml and were randomly divided into three groups receiving different doses of vitamin D .

Main outcome variables

The most important outcome evaluated in this study is the response to vitamin D treatment in pregnant women.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211101052937N1**

Registration date: **2021-12-28, 1400/10/07**

Registration timing: **retrospective**

Last update: **2021-12-28, 1400/10/07**

Update count: **0**

Registration date

2021-12-28, 1400/10/07

Registrant information

Name

fatemeh Sadri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3222 1761

Email address

fatemeh.sadri1374@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

2021-01-25, 1399/11/06

Actual recruitment end date

2021-10-22, 1400/07/30

Trial completion date

2021-10-22, 1400/07/30

Scientific title

Assessment of optimal vitamin D dose for treatment of hypovitaminosis D in pregnant women

Public title

The effect of vitamin D in the treatment of vitamin D deficiency

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

18-45 years gestational age of less than 14 weeks
vitamin D levels below 20 ng / ml

Exclusion criteria:

Fetal abnormalities Abortion زایمان قبل از 20 هفته Lack of cooperation of the mother in receiving treatment Kidney disorders in pregnant women Blood pressure in pregnant women Diabetes in pregnant women

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **55**

Actual sample size reached: **57**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into three groups of 19 using random allocation software. From the first patient with inclusion criteria, treatment allocation was started based on randomization and all underwent the prescribed drug treatment. Initially, the numbers 1 to 57 were written on 57 envelopes, respectively. Then, in each envelope, a sheet containing the code of the type of treatment of each patient, which is specified based on the random allocation software and determines the treatment of each patient, and the written consent form of the study participant was placed. After entering or identifying each patient in accordance with the criteria for entering an envelope, the numbers were selected in the order in which the type of treatment was specified in code.

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 Shahroud Azad University

Street address

7th sub. Third Alley. Shahrebani st.

City

Shahrood

Province

Semnan

Postal code

3616637333

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1399.069

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

Vitamin D deficiency

ICD-10 code

E55.0

ICD-10 code description

Rickets, active

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

vitamin D insufficiency

Timepoint

Pregnant mother under 18 weeks

Method of measurement

evaluation of vit D blood serum

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Vitamin D administration at a dose of 2000

Category

Treatment - Drugs

2**Description**

Intervention group: Vitamin D administration at a dose of 4000

Category

Treatment - Drugs

3**Description**

Control group: Vitamin D administration at a dose of

1000
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahroud Bahar Hospital Clinic
Full name of responsible person
Dr Mina Kohbodi
Street address
Bahar Hospital, 22 Bahman St.
City
Shahrood
Province
Semnan
Postal code
3616637333
Phone
+98 58 3623 5480
Email
fatemeh.sadri1374@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Behrooz Yahyaei
Street address
sub7, 3rd Alley, Shahr bani St.
City
Shahrood
Province
Semnan
Postal code
3616637333
Phone
+98 58 3623 5480
Email
fatmeh.sadri1374@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Shahroud University of Medical Sciences
Full name of responsible person
Mina Kohbodi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
7th sub, 3rd Alley, Shahr bani St.
City
Shahrood
Province
Semnan
Postal code
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Phone
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Email
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Person responsible for scientific inquiries

Contact

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Shahroud University of Medical Sciences
Full name of responsible person
Mina Kohbodi
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Gynecology and Obstetrics
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Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences

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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

more information does not exist

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available