Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 هفته 20 از قبل زایمان 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 insuffiency
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, Shahrbani 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, Shahrbani St.

City

Shahrood

Province

Semnan

Postal code

3616637333

Phone

+98 58 3623 5480

Email

fatmeh.sadri1374@gmail.com

Person responsible for scientific 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, Shahrbani st.

City

Shahrood

Province

Semnan

Postal code

3616637333

Phone

+98 58 3623 5480

Email

fatmeh.sadri1374@gmail.com

Person responsible for updating data

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, Shahrbani st.
City
Shahrood
Province
Semnan
Postal code
3616637333
Phone
+98 58 3623 5480
Email
fatmeh.sadri1374@gmail.com

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