Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Vitamin D Status and Response to Vitamin D3 (50000 unit supplementation) in pregnant Iranian woman

Protocol summary

Study aim

The aim of this study was to identify the prevalence of vitamin D deficiency in an Iranian pregnant population and to analyze the impact of implementing a screening and treatment protocol by Vitamin D3 (50000 unit supplementation) among them.

Design

This is conducted at a prenatal care clinic in Tehran, Iran. Of total 357 pregnant women, 249 patients had first trimester and 278 had third trimester vitamin D level. The final sample size of this study was 216. The screening for vitamin D deficiency was typically performed at two points throughout prenatal care: one at the initial prenatal visit and another at approximately 28 weeks' gestation. If Vitamin D status was insufficient an additional vitamin D3 supplement of 50,000 IU of ergocalciferol was prescribed weekly for 10 weeks. Due to ethical issues, the control group without the supplementation was removed .

Settings and conduct

This study designed and conducted at a prenatal care clinic in Tehran, Iran. 357cases were identified.

Participants/Inclusion and exclusion criteria

inclusion criteria: (1) maternal age of 16 years or greater at the time of consent, (2) confirmed singleton pregnancy of less than 16 weeks' gestation at the time of consent, (3) planned to receive ongoing prenatal care in our prenatal clinic in Tehran, (4) they had at least two measurements of vitamin D levels in the first or second trimesters and in the third trimester. Exclusion criteria included twin pregnancy, maternal immune deficiency disease, and a history of gastric bypass surgery.

Intervention groups

If Vitamin D status was insufficient an additional vitamin D3 supplement of 50,000 IU of ergocalciferol was prescribed weekly for 10 weeks.

Main outcome variables

change of vitamin D level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170714035077N3**
Registration date: **2018-01-29, 1396/11/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-29, 1396/11/09**
Update count: **0**

Registration date

2018-01-29, 1396/11/09

Registrant information

Name

tahmineh ezazi Bojnordi

Name of organization / entity

North khorasan univercity of medical sience

Country

Iran (Islamic Republic of)

Phone

+98 58 3222 1635

Email address

ezazi.t@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tahmineh Ezazi Bojnordi

Expected recruitment start date

2017-03-19, 1395/12/29

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Vitamin D Status and Response to Vitamin D3 (50000 unit supplementation) in pregnant Iranian woman

Public title
The vitamin D deficiency in pregnancy: prevalence and treatments

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Maternal age of 16 years or greater at the time of consent Confirmed singleton pregnancy of less than 16 weeks' gestation at the time of consent Planned to receive ongoing prenatal care in our prenatal clinic in Tehran They had at least two measurements of vitamin D levels in the first or second trimesters and in the third trimester

Exclusion criteria:
Twin pregnancy Maternal immune deficiency disease A history of gastric bypass surgery

Age
From **16 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **357**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
We have one group and intervention for everyone is the same.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran Univercity of Medical Sciences

Street address
emem khomeini hospital, tohid square,Tehran, Iran

City
tehran

Province
Tehran

Postal code
1419733141

Approval date
2017-09-10, 1396/06/19

Ethics committee reference number
IR.TUMS.REC:96-02-30-35934

Health conditions studied

1

Description of health condition studied
vitamin D deficiency

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Level of vitamin D

Timepoint
After 24 weeks

Method of measurement
Level in blood sample

Secondary outcomes

empty

Intervention groups

1

Description
vitamin D3 supplement of 50,000 IU of ergocalciferol was prescribed weekly for 10 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
prenatal care clinic Emam Khomeini hospital in Tehran, Iran

Full name of responsible person
tahmineh ezazi Bojnordi

Street address
Emam Khomaini hospital, Tohid squer, Tehran, Iran

City
tehran

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1419733141

Phone

+98 21 2217 2614

Email

tahmine_ezazi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhondzadeh

Street address

Room 206, first floor, medical School, Tehran, Iran

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Fax

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Email

s.akhond@neda.net

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Tahmine Ezazi Bojnordi

Position

OBG, MD, spesialist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Emam Khomaini hospital, Tohid squer, Tehran, Iran

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ezazi.t@nkums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

OBG

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people.

When the data will become available and for how long

1398

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

For research or therapeutic use Mention the name of the related institution or research center and her/his position in the center and the purpose of the data request

From where data/document is obtainable

Contact Dr. Tahmineh Ezazi by email tahmine_ezazi@yahoo.com

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

If the request is for research purpose, it will be emailed to the requestor within one week

Comments