Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Compare the effect of vitamin D and calcium plus vitamin D on pregnancy outcomes in pregnant women

Protocol summary

Summary

Objective: To determine the effect of vitamin D3 supplementation on pregnancy outcomes Study design: one blind randomized. Study population: this study is a randomized single blind controlled clinical trial undertaken on 460 pregnant women between 20-40 ages who refereed to women clinic of shariati Hospital of Bandarabas , Iran from 2015-2016. Inclusion criteria: Gestational age less than 10 weeks of gestation; with no history of diabetes; hypertension; a history of polycystic ovary syndrome; lack of family history of diabetes in first-degree relatives; no family history of high blood pressure in first-degree relatives; tend the sick; the vitamin D <30ng / L in patients 10-6 weeks of pregnancy; body mass index between 19-26; lack of vitamin D during the last 6 months; singleton pregnancy; gestational first to third; Iran. Exclusion criteria: Unwillingness to participate in the study. Sample size: 460. Intervention: In intervention group is used vitamin D3 1000unit oral daily since 16weeks until the end of pregnancy. They also prescribed as routine prenatal care multi vitamin that has 400unit Vitamin D-ca since 16 weeks of pregnancy. The control group is used multi vitamin that has 400unit Vitamin D daily until the end of pregnancy. Time intervention: From 16 weeks gestation until the end of pregnancy Primary outcomes: Vitamin D concentration in the serum, diabetes, preeclampsia, preterm delivery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121430612N2**
Registration date: **2016-12-26, 1395/10/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-26, 1395/10/06

Registrant information

Name
Najmehsadat Mosalanejad
Name of organization / entity
Hormozgan University of Medical Sciences
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Email address
mosalanejad@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of vitamin D and calcium plus vitamin D on pregnancy outcomes in pregnant women

Public title

The effect of vitamin D3 supplement on pregnancy outcomes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age less than 10 weeks of gestation; with no history of diabetes; hypertension; a history of polycystic ovary syndrome; lack of family history of diabetes in first-degree relatives; no family history of high blood pressure in first-degree relatives; tend the sick; the vitamin D <30ng / L in patients 10-6 weeks of pregnancy; body mass index between 19-26; lack of vitamin D during the last 6 months; singleton pregnancy; gestational first to third; Iran. Exclusion criteria: Unwillingness to participate in the study.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **460**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hormozgan University of Medical Sciences

Street address
No. 7916839319, Vice chancellor for research, Shahid Mohammadi Hospital, Bandarabbas

City
Bandarabbas

Postal code

Approval date
2016-05-18, 1395/02/29

Ethics committee reference number
HUMS.REC.1395.029

Health conditions studied

1

Description of health condition studied
Vitamin D deficiency

ICD-10 code
E55

ICD-10 code description
Vitamin D deficiency

Primary outcomes

1

Description
Vitamin D concentration in serum of pregnant women

Timepoint
Third trimester of pregnancy

Method of measurement
Blood exam

Secondary outcomes

1

Description
Diabete

Timepoint
since 16weeks until the end of pregnancy

Method of measurement
The record information of pregnant women

2

Description
Preeclamsia

Timepoint
since 16weeks until the end of pregnancy

Method of measurement
The record information of pregnant women

3

Description
Preterm delivery

Timepoint
since 16weeks until the end of pregnancy

Method of measurement
The record information of pregnant women

Intervention groups

1

Description
Control group: Ca-D supplement contains 400 UI vitamin D daily from 16 weeks until the end of the pregnancy was received.

Category
Prevention

2

Description
Intervention group: Vitamin D3 daily, oral 1000UI from 16 weeks until the end of the pregnancy is used. Also, this group according to routine prenatal care, ca-D supplement contains 400 UI vitamin D daily from 16

weeks until the end of the pregnancy was received.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Women Clinic of Shariati Hospital

Full name of responsible person

Dr Najmehsadat Mosalanejad

Street address

City

Bandarabbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Teymor Aghamolaei

Street address

No. 7916839319, Vice chancellor for research, Shahid Mohammadi Hospital, Bandarabbas

City

Bandarabbas

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hormozgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Dr Najmehsadat Mosalanejad

Position

Ph.D student

Other areas of specialty/work

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Other areas of specialty/work

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty