

# 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 referred 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 76 3333 7192

###### 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**

**Street address**

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**Fax**

**Email**

**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*