

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of 50000 IU Vitamin D supplement administered two weekly on neonatal and pregnant women outcome

#### Protocol summary

##### Summary

This study is a Randomized clinical trial conducted on 440 pregnant women who referred to pregnancy clinic of Shahid Sadoughi and Mojibian parathyroid Hospitals. The study population were randomly divided in two groups. Case group received 50000 IU of Vitamin D every 2 weeks and control group received 200 IU vitamin D3 daily. Blood samples were taken after 8 hours fasting. After serum extraction, samples were stored at -70 C until collection of all samples to measurement of serum 25-OHD. For all pregnant women screening for diabetes with a 75 gr oral glucose tolerance test and in 0, 1 & 2 hours (GTT) were done, Subjects with plasma glucose concentrations of one or more than 92 in 0, 180 in 1 & 153 in 2 hours were assumed positive for gestational diabetes. Inclusion criteria: all pregnant women came to prenatal clinic of Shahid Sadoughi and Mojibian Hospitals during first trimester with no history of corticosteroids or anticonvulsants use during the last 6 months were involved after blood sample taken for measurement of vitamin D serum level and were randomly assigned to two groups Exclusion criteria any person with history of thyroid or parathyroid diseases, receiving vitamin D more than maintenance dose during last 6 months, treated with corticosteroids or anticonvulsants and history of diabetes mellitus before pregnancy.

#### General information

##### Acronym

GDM

##### IRCT registration information

IRCT registration number: **IRCT201107237097N1**

Registration date: **2012-02-27, 1390/12/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-02-27, 1390/12/08

##### Registrant information

###### Name

Mahdiyeh Mojibian

###### Name of organization / entity

Obstetric and Gynecology department

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 1822 4000

###### Email address

m.mojibian@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi Yazd University of Medical Sciences

##### Expected recruitment start date

2011-07-23, 1390/05/01

##### Expected recruitment end date

2012-03-19, 1390/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of 50000 IU Vitamin D supplement administered two weekly on neonatal and pregnant women outcome

##### Public title

The effect of 50000 IU Vitamin D supplement administered two weekly on gestational Diabetes Mellitus

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

All pregnant women who came to prenatal clinic of Shahid Sadoughi and Mojibian Hospitals during first trimester with no history of corticosteroids or anticonvulsants use during the last 3 months were included. Exclusion criteria: history of thyroid or parathyroid diseases; receiving vitamin D more than maintenance dose during the last 6 months; treatment with corticosteroids or anticonvulsants and history of diabetes mellitus before pregnancy.

#### Age

From **15 years** old to **48 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **440**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Shahid Sadoughi Yazd University of Medical Sciences

###### Street address

Bahonar SQ - Yazd

###### City

Yazd

###### Postal code

###### Approval date

2011-06-26, 1390/04/05

###### Ethics committee reference number

39312

### Health conditions studied

#### 1

##### Description of health condition studied

Gestational DM

##### ICD-10 code

O24.4

##### ICD-10 code description

Gestational diabetes mellitus NOS

#### 2

##### Description of health condition studied

VitD deficiency

##### ICD-10 code

E55.9

##### ICD-10 code description

Vitamin D deficiency, unspecified

### Primary outcomes

#### 1

##### Description

Vit D

##### Timepoint

First trimester

##### Method of measurement

Blood sample test

### Secondary outcomes

#### 1

##### Description

Gestational DM

##### Timepoint

First trimester

##### Method of measurement

Blood test

### Intervention groups

#### 1

##### Description

Intervention group: vitamin D supplement, 50000u tab, every 2 weeks

##### Category

Prevention

#### 2

##### Description

Control group: vitamin D Supplement, Calcium-D tablet, 200 IU daily

##### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Baghaipour Clinic

###### Full name of responsible person

Mrs Naghshin

###### Street address

**City**  
Yazd

**2**

**Recruitment center**

**Name of recruitment center**  
Gynecology Clinic of Mojibian Hospital  
**Full name of responsible person**  
Dr Maryam Jannati Moghaddam  
**Street address**  
**City**  
Yazd

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**  
Shahid Sadughi Yazd University of Medical Sciences  
**Full name of responsible person**  
Dr. Fatemeh Ezoddini  
**Street address**  
Bahonar sq.  
**City**  
Yazd

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Sadughi Yazd 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**  
Dr Mojibian hospital  
**Full name of responsible person**  
Dr Maryam Jannati Moghadam  
**Position**  
GP  
**Other areas of specialty/work**  
**Street address**  
Ayatollah kashani ST  
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8915635843

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+98 35 1624 0061

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m\_janaty\_m@yahoo.com

**Web page address**  
www.drmojibian.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**  
Shahid Sadoughi University of Medical Science- Yazd  
diabetics research center

**Full name of responsible person**  
Dr Sedighe Soheilikhah

**Position**  
Assistant professor

**Other areas of specialty/work**

**Street address**  
Safayie, Shahid Ghandi blv, Shahid Sadughi Hospital

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s\_soheilykhah@yahoo.com

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**Person responsible for updating data**

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Mojibian Hospital  
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Dr Maryam Janati Moghadam

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**Other areas of specialty/work**

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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*