

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effectiveness of different Prescription Method of Vitamin D3 on Obstetric and Early Neonatal Outcomes in Pregnant Women with Vitamin D deficiency

#### Protocol summary

##### Study aim

Effectiveness of different Prescription Method of Vitamin D3 on Obstetric and Early Neonatal Outcomes in Pregnant Women with Vitamin D deficiency

##### Design

In the second phase of the study, to assess the effect of screening strategy on maternal and neonatal outcomes, Masjed-Soleyman participants were assigned to a screening program versus Shushtar participants acting as the nonscreening arm. Within the framework of the screening regimen, an 8-arm blind randomized clinical trial was undertaken to compare the effects of various treatment protocols. Due to the cost and complexity of the process, 800 pregnant women with vitamin D deficiency from Masjed-Soleyman were randomly allocated to 1 of the designed intervention programs. The remaining women with vitamin D deficiency were referred to specialists for further treatments. Participants of Shushtar did not receive any vitamin D supplementation. However, the comparison of the basic confounders between the initial recruited sample in Masjed-Soleyman and the women allocated to intervention indicated no statistically significant difference and hence no selection bias occurred during the allocation of treatment. Women with severe vitamin D deficiency (Group A) Group A1: Subjects were treated with 50,000 IU of oral vitD3 weekly for a total duration of 12 weeks. Group A2: Subjects were treated with 50,000 IU of oral vitD3 weekly for a total duration of 12 weeks and then were on monthly maintenance dose of 50,000 IU vitD3 until delivery. Group A3: Subjects were treated with intramuscular administration of 300,000 IU vitD3; 2 doses for 6 weeks. Group A4: Subjects were treated with Intramuscular administration of 300,000 IU vitD3; 2 doses for 6 weeks and then were on monthly maintenance dose of 50,000 IU vitD3 until delivery. Women with moderate vitamin D deficiency (Group B)

Group B1: Subjects were treated with 50,000 IU oral vitD3 weekly for a total duration of 6 weeks. Group B2: Subjects were treated with 50,000 IU oral vitD3 weekly for a total duration of 6 weeks and then were on monthly maintenance dose of 50,000 IU vitD3 until delivery. Group B3: Subjects were treated with a single dose of intramuscular administration of 300,000 IU vitD3. Group B4: Subjects were treated with a single dose of Intramuscular administration of 300,000 IU vitD3 and then were on monthly maintenance dose of 50,000 IU vitD3 until delivery.

##### Settings and conduct

Using the cluster sampling method, 1600 and 900 first trimester mothers were selected from among those receiving prenatal care in health centers in urban regions of Masjed-Soleyman and Shushtar, respectively. Subjects in each group of severe or moderate deficiencies were randomly divided into 4 subgroups using permuted block randomization by a biostatistician to achieve balance across treatment groups. The number of subjects per block was 8. Sealed opaque envelopes were assigned to each subject by a research assistant not associated in the trial. The dedicated study midwife treating the females, who did not participate in any subsequent phases of the study, was the only person who knew the group each patient belonged to (single blinded). Masking to treatment allocation was not possible and only those health care workers who determined pregnancy outcomes were blinded to treatment allocation.

##### Participants/Inclusion and exclusion criteria

Pregnant women, aged 18-40 years, were eligible if they had gestational age <14 weeks based on last menstrual period or obstetrical estimation, singleton pregnancy, and had planned to receive ongoing prenatal and delivery in the Masjed-Soleiman. Participants were excluded if they consumed multivitamins containing more than 400 international unit (IU) per day of vitamin D3; used anticonvulsants; and had history of chronic diseases like diabetes, hypertension, renal dysfunction,

liver diseases, and complicated medical or obstetrical history.

### Intervention groups

Women with severe vitamin D deficiency (Group A)  
Group A1: Subjects were treated with 50,000 IU of oral vitD3 weekly for a total duration of 12 weeks. Group A2: Subjects were treated with 50,000 IU of oral vitD3 weekly for a total duration of 12 weeks and then were on monthly maintenance dose of 50,000 IU vitD3 until delivery. Group A3: Subjects were treated with intramuscular administration of 300,000 IU vitD3; 2 doses for 6 weeks. Group A4: Subjects were treated with Intramuscular administration of 300,000 IU vitD3; 2 doses for 6 weeks and then were on monthly maintenance dose of 50,000 IU vitD3 until delivery.  
Women with moderate vitamin D deficiency (Group B)  
Group B1: Subjects were treated with 50,000 IU oral vitD3 weekly for a total duration of 6 weeks. Group B2: Subjects were treated with 50,000 IU oral vitD3 weekly for a total duration of 6 weeks and then were on monthly maintenance dose of 50,000 IU vitD3 until delivery. Group B3: Subjects were treated with a single dose of intramuscular administration of 300,000 IU vitD3. Group B4: Subjects were treated with a single dose of Intramuscular administration of 300,000 IU vitD3 and then were on monthly maintenance dose of 50,000 IU vitD3 until delivery.

### Main outcome variables

Primary endpoints are to find out the beneficiary impact of screening of pregnant women for vitamin D deficiency on pregnancy and neonatal outcomes and assessing the effect of supplementation with vitamin D on these outcomes.

## General information

### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2014102519660N1**  
Registration date: **2015-01-22, 1393/11/02**  
Registration timing: **prospective**

Last update: **2018-01-19, 1396/10/29**

Update count: **1**

#### Registration date

2015-01-22, 1393/11/02

#### Registrant information

##### Name

Maryam Rostami

##### Name of organization / entity

Shahid Beheshti Medical University School of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 68 1222 5471

##### Email address

m\_rostami@sbmu.ac.ir

### Recruitment status

### Recruitment complete

#### Funding source

Endocrine Research Center Shahid Beheshti University of Medical Sciences

#### Expected recruitment start date

2014-12-01, 1393/09/10

#### Expected recruitment end date

2016-01-01, 1394/10/11

#### Actual recruitment start date

2015-02-10, 1393/11/21

#### Actual recruitment end date

2016-03-10, 1394/12/20

#### Trial completion date

empty

#### Scientific title

Effectiveness of different Prescription Method of Vitamin D3 on Obstetric and Early Neonatal Outcomes in Pregnant Women with Vitamin D deficiency

#### Public title

Comparison the Effectiveness of different Prescription Method of Vitamin D3 on Obstetric and Early Neonatal Outcomes in Pregnant Women with Vitamin D deficiency.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Pregnant women Current residence in Masjed Soleyman Gestational age under 14 weeks Maternal age 18-40 years Singleton pregnancy

##### Exclusion criteria:

Diabetes Chronic hypertension Thyroid diseases Renal dysfunction Cardiovascular diseases Current use of anticonvulsant drugs Phenytoin Carbamazepine Steroidal drugs Anti cholesterol Digoxin Use of any dietary supplement containing more than 400 IU/day of vitamin D

#### Age

From **18 years** old to **40 years** old

#### Gender

Female

#### Phase

1

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **800**

Actual sample size reached: **800**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Subjects in each group of severe or moderate deficiencies were randomly divided into 4 subgroups using permuted block randomization by a biostatistician to achieve balance across treatment groups. The number of subjects per block was 8. Sealed opaque envelopes were assigned to each subject by a research assistant not associated in the trial.

#### Blinding (investigator's opinion)

Single blinded

### Blinding description

The dedicated study midwife treating the females, who did not participate in any subsequent phases of the study, was the only person who knew the group each patient belonged to (single blinded). Masking to treatment allocation was not possible and only those health care workers who determined pregnancy outcomes were blinded to treatment allocation.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee of Shahid Beheshti Medical University

##### Street address

No 24, Parvaneh Street, Yaman Street, Velenjak, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717413

#### Approval date

2013-12-16, 1392/09/25

#### Ethics committee reference number

490-10ECRIES92/10/25

## Health conditions studied

### 1

#### Description of health condition studied

Vitamin D deficiency

#### ICD-10 code

E55

#### ICD-10 code description

Avitaminosis D

## Primary outcomes

### 1

#### Description

Abortion

#### Timepoint

In intervention

#### Method of measurement

Yes/ No

### 2

#### Description

Preterm Labour

#### Timepoint

In intervention

#### Method of measurement

Yes/ No

### 3

#### Description

Gestational Diabetes

#### Timepoint

In intervention

#### Method of measurement

Yes/ No

### 4

#### Description

Preeclampsia

#### Timepoint

In intervention

#### Method of measurement

Yes/ No

### 5

#### Description

Serum 25(OH)D concentration in mother

#### Timepoint

In intervention

#### Method of measurement

Ng/ml

## Secondary outcomes

### 1

#### Description

Birth weight

#### Timepoint

after intervention

#### Method of measurement

gr

### 2

#### Description

Head circumference

#### Timepoint

After intervention

#### Method of measurement

Cm

### 3

#### Description

Cord blood 25(OH)D level

#### Timepoint

After intervention

#### Method of measurement

Ng/ml

#### 4

##### **Description**

Birth Length

##### **Timepoint**

After intervention

##### **Method of measurement**

Cm

#### 5

##### **Description**

Cord blood Calcium

##### **Timepoint**

After intervention

##### **Method of measurement**

Ng/ml

#### 6

##### **Description**

Apgar Score 1 minute and 5 minute

##### **Timepoint**

After intervention

##### **Method of measurement**

Standard Apgar Score

#### 7

##### **Description**

Fall of umbilical cord time

##### **Timepoint**

After intervention

##### **Method of measurement**

Day

#### 8

##### **Description**

Neonatal Ecterus

##### **Timepoint**

After intervention

##### **Method of measurement**

Mg/dl

## **Intervention groups**

#### 1

##### **Description**

Control group C: Subjectes are observed only about outcomes with no intervention.-9

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

6- Internention group B1,2 : Subjects are treated with 50000IU oral vitD3 weekly for a total duration of 6 weeks and then termination of intervention(100)

##### **Category**

Treatment - Drugs

#### 3

##### **Description**

7-Intervention group B2,1 :Subjects(200) are treated with Intramascular administration of 300000 IU vitD3 for 1 dose and after 6 weeks they recive 50000IU oral vitaminD3 monthly until delivey.

##### **Category**

Treatment - Drugs

#### 4

##### **Description**

8-Intervention group B2,2 :Subjects(200) are treated with Intramascular administration of 300000 IU vitD3 for 1 dose and then termination of intervention(100).

##### **Category**

Treatment - Drugs

#### 5

##### **Description**

2-Intervention group A1,2:Subjects are treatedd with 50000IU oral vitaminD3 weekly for a total duration of 12 weeks and then termination of intervention(100).

##### **Category**

Treatment - Drugs

#### 6

##### **Description**

3-Intervention groupA2,1: Subjects are treated with Intramascular administration of 300000 IU vitaninD3 each 6 week for 2 doses and then they recive 50000IU oral vitaminD3 monthly until delivery(100).

##### **Category**

Treatment - Drugs

#### 7

##### **Description**

5- Internention group B1,1 : Subjects are treated with 50000IU oral vitD3 weekly for a total duration of 6 weeks and they recive 50000IU oral vitaminD3 monthly until delivery(100).

##### **Category**

Treatment - Drugs

#### 8

##### **Description**

4-Intervention groupA2,2: Subjects are treated with Intramascular administration of 300000 IU vitaminD3 each 6 week for 2 doses and then termination of intrevention(100).

##### **Category**

Treatment - Drugs

**9**

**Description**

1-Intervention group A1 ,1: Subjects are treated with 50000IU oral vitD3 weekly for a total duration of 12 weeks and they recive 50000IU oral vitD3 monthly until delivery(100).

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Endocrine Reseach Center Shahid beheshti  
University of Medical Sciences

**Full name of responsible person**

Dr Fahimeh Ramezani Tehrani

**Street address**

No 24, Parvaneh Street, Yaman Street, Velenjak,  
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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Medical Sciences for Research of Shahid Beheshti  
Medical university

**Full name of responsible person**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Medical Sciences for Research of Shahid Beheshti  
Medical university

**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**

School of Nursing and Midwifery Shahid Beheshti  
Medicl University

**Full name of responsible person**

Maryam Rostami

**Position**

PhD Student of Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Endocrine Reseach Center Shahid beheshti  
University of Medical Sciences

**Full name of responsible person**

Dr Farhad Hossein panah

**Position**

Chief of the endocrine DPT

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Yet not decided.

### When the data will become available and for how long

Yet not decided.

### To whom data/document is available

Yet not decided.

### Under which criteria data/document could be used

Yet not decided.

### From where data/document is obtainable

Yet not decided.

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

Yet not decided.

### Comments