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 MedicalUniversity 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 age18-40 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 Lobour

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 weigth

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 Lenght
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 treatded 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 Reseatch 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, Tehran
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2500
Email
m6326726@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Medical Sciences for Research of Shahid Beheshti Medical university
Full name of responsible person
Dr Fahimeh Ramezani Tehrani
Street address
No 24, Parvaneh Street, Yaman Street, Velenjak, Tehran
City
No 24, Parvaneh Street, Yaman Street, Velenjak, Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2500
Email
m6326726@gmail.com
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
Street address
No 7,Phase 1 of Farhangiam,
City
Masjed Soleyman
Province
Khouzestan
Postal code
6491796581
Phone
+98 68 1222 5471
Fax
Email
m6326726@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Endocrine Reseatch 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
Street address
No 24, Parvaneh Street, Yaman Street, Velenjak,

Tehran

City
Tehran

Province
Tehran

Postal code
1985717413

Phone
+98 21 2243 2500

Fax

Email
farhad.hosseinpanah@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Nursing and Midwifery Shahid Beheshti Medicl

Full name of responsible person
Maryam Rostami

Position
PhD Student of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
School of Nursing and Midwifery Shahid Beheshti Medicl

City
Tehran

Province
Khouzestan

Postal code
6491796581

Phone
+98 21 2243 2500

Fax

Email
m6326726@gmail.com

Web page address

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