

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Clinical Trial on the Evaluation of Calcium and Vitamin D in the Cord Serum of Neonates, Whose Mothers Were Under Vitamin D Treatment During Their Pregnancy

Protocol summary

Summary

The population of this study includes all neonates of pregnant women who are in the age of 16 to 35 years old and among 14 to 16 weeks of pregnancy referred to Amiral-mo'menin Hospital in 1393 to take prenatal care. Two groups of 90 pregnant mothers which determined with vitamin D deficiency, concerning inclusion and exclusion criteria, were selected and named intervention and control groups. Intervention group was given 8 doses of vitamin D pearls every two weeks; each dose contains 50000 units, plus multi prenatal tablet including 400 units of vitamin D, every day. Also, the control group only received the multi prenatal tablet, every day. The methods which were used in collecting data are demographic questionnaire and recording data check-lists which were filled with laboratory assessments. Additionally, this is a single blinded study that include just research groups. In order to collect data, three milliliters of cord blood in related tubes were collected, in the time of childbirth. Then, they were transferred to the laboratory of Semnan Amir al-mo'menin Hospital and the level of serum 25-OH vitamin D and calcium were evaluated with England Euroimneun and Semnan Rezateb kits using ELISA method, respectively.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015041321736N1**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Shamsollah Nooripour

Name of organization / entity

Amiralmomenin Hospital

Country

Iran (Islamic Republic of)

Phone

+98 23 3346 0077

Email address

amir.hospital@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Semnan University of Medical Science

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial on the Evaluation of Calcium and Vitamin D in the Cord Serum of Neonates, Whose Mothers Were Under Vitamin D Treatment During Their Pregnancy

Public title

Evaluation of Calcium and Vitamin D in Neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant mothers with vitamin D deficiency; age of 16-35 years; singleton pregnancy; gestational age of among 8 to 12 weeks which is confirmed by LMP or sonography; BMI lower than thirty at the first prenatal visit; no history of gestational diabetes; not suffering from glycosuria, fasting blood sugar less than 92; no precedent of polyhydramnios; no history of macrosomia (weight of 4 kg) in children; with no history of stillbirth or a baby with malformations; non-smoking participants. Exclusion criteria: patients with diabetes type one or two; those with hypertension; patients with parathyroid disease and other metabolic diseases; people with untreated thyroid disease and liver or kidney deficiency; patients taking anti-epileptic drugs and corticosteroids; and people with a particular disease. Also, those who refuse consent for participating in this study, will be excluded.

Age

From **16 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **180**

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

Ethic committee of Semnan University of Medical Science

Street address

5th kilometers of Damghan road, Semnan- Iran.

City

semnan

Postal code

35198-99951

Approval date

2015-03-17, 1393/12/26

Ethics committee reference number

93.584644

Health conditions studied

1

Description of health condition studied

vitamin D deficiency

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

Primary outcomes

1

Description

25oH vitamin D3

Timepoint

daily

Method of measurement

mg/dl

2

Description

Calcium

Timepoint

daily

Method of measurement

mg/dl

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

injection of 50000 units of vitamin D, eight doses every two weeks

Category

Treatment - Drugs

2

Description

In the control group, multi natal tab including 400 units of vitamin D was taken every day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al-momenin hospital

Full name of responsible person

Dr. Nouripour

Street address

Management office of Amir al-momenin Hospital,
Imam Hossein Square, Semnan, Iran.

City

Semnan

Amir al-mo'menin Hospital, Imam Hossein Square,
Semnan- Iran.

City

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Postal code

Phone

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Fax

-

Email

sh.noripour@yahoo.com

Web page address

amir.hospital@semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Semnan University of medical
science

Full name of responsible person

Dr. Nouripour

Street address

Management office of Amir al-mo'menin Hospital,
Imam Hossein Square, Semnan- Iran.

City

Semnan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor of Semnan University of medical science

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

Amir al-mo'menin Hospital

Full name of responsible person

Dr. Shamsollah Nouripour

Position

Advisor professor, neonatologist

Other areas of specialty/work

Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Science

Full name of responsible person

Dr. Nouripour

Position

neonatologist

Other areas of specialty/work

Street address

Management office of Amir al-mo'menin Hospital,
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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Science

Full name of responsible person

Dr. Nouripour

Position

neonatologist

Other areas of specialty/work

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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