

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the efficacy of vitamin D supplementation during pregnancy on maternal and newborn vitamin D status and pregnancy outcomes compared with control group

Protocol summary

Summary

Aim: Evaluation the efficacy of vitamin D supplementation during pregnancy on maternal and newborn vitamin D status and pregnancy outcomes compared Study design: Randomized Controlled Trial without placebo, Study population: Pregnant women aged at 18-40 years and their newborns. Inclusion criteria: Pregnant women aged at 18-40 years and their newborns, Singleton pregnancy. Exclusion criteria: Multiple pregnancy, Diagnosis any kind of diseases including renal, hepatic, and other disorders which could influence vitamin D metabolism during the study, Chronic hypertension, Receiving vitamin D or calcium supplements within the last three months, On any medication which could potentially influence vitamin D metabolism (notably estrogens, and calcitonin) within the last three months, Newborns with congenital anomalies. Sample size: 126 Intervention: Control group: Current supplements during pregnancy (Iron, Folic acid, Multivitamin), Intervention group 1: Current supplements during pregnancy (Iron, Folic acid, Multivitamin) + vitamin D (1000 IU/d), Intervention group 2: Current supplements during pregnancy (Iron, Folic acid, Multivitamin) + vitamin D (2000 IU/d). Duration of intervention: First trimester until delivery Primary outcome: Vitamin D concentration of maternal serum and cord blood Secondary outcome: Preeclampsia, Gestational diabetes, Preterm delivery, Abortion, Growth indices of newborns.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090329675N1**

Registration date: **2016-09-25, 1395/07/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-25, 1395/07/04

Registrant information

Name

Soudabe Motamed

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
School of Nutrition Sciences and Food Technology, Na

Country

Iran (Islamic Republic of)

Phone

+98 21 2209 7419

Email address

s_motamed@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences, National
Nutrition and Food Technology Research Institute

Expected recruitment start date

2016-10-11, 1395/07/20

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of vitamin D supplementation during pregnancy on maternal and newborn vitamin D status and pregnancy outcomes compared with control group

Public title

Effect of vitamin D supplementation on the pregnancy outcomes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women aged at 18-40 years and their newborns, Singleton pregnancy. Exclusion criteria: Multiple pregnancy, Diagnosis any kind of diseases including renal, hepatic, and other disorders which could influence vitamin D metabolism during the study, Chronic hypertension, Receiving vitamin D or calcium supplements within the last three months, On any medication which could potentially influence vitamin D metabolism (notably estrogens, and calcitonin) within the last three months, Newborns with congenital anomalies.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Considering the inclusion and exclusion criteria, pregnant women will participate in this study, then participants are randomly attributed to three groups including two intervention groups and one control group using Random-number table.

Secondary Ids**1****Registry name**

no registration

Secondary trial Id

no registration

Registration date

empty

2**Registry name**

no registration

Secondary trial Id

no registration

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of International Branch of Shahid Behesti University of Medical Sciences and Health

Street address

No. 19, Shahid abbaspour St., vali-asr Av., Tehran, Iran.

City

Tehran

Postal code

1434875451

Approval date

2016-01-17, 1394/10/27

Ethics committee reference number

IR.SBMU.IASB.REC

Health conditions studied**1****Description of health condition studied**

Pre-eclampsia

ICD-10 code

O14.9

ICD-10 code description

Pre-eclampsia, unspecified

2**Description of health condition studied**

Vitamin D status in pregnant women and cord blood

ICD-10 code

E55

ICD-10 code description

E55: Vitamin D deficiency

3**Description of health condition studied**

Gestational Diabetes Mellitus

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in pregnancy (Gestational diabetes mellitus NOS)

4**Description of health condition studied**

Preterm delivery

ICD-10 code

O60

ICD-10 code description

Preterm labour and delivery

5

Description of health condition studied

Abortion

ICD-10 code

O60

ICD-10 code description

Spontaneous abortion

Primary outcomes

1

Description

Vitamin D concentration of pregnant women serum

Timepoint

Baseline and after the intervention

Method of measurement

High performance liquid chromatography (HPLC)

2

Description

Vitamin D concentration of Cord blood

Timepoint

At birth

Method of measurement

High performance liquid chromatography (HPLC)

Secondary outcomes

1

Description

Growth indices of newborns

Timepoint

After Birth

Method of measurement

Infant's Records

2

Description

Preterm delivery

Timepoint

At less than 37 weeks of gestational age

Method of measurement

Pregnant women Records

3

Description

Abortion

Timepoint

During the first 28 weeks of pregnancy

Method of measurement

Pregnant women Records

4

Description

Gestational diabetes

Timepoint

At the gestational age of 24-28 weeks

Method of measurement

Pregnant women Records

5

Description

Preeclampsia

Timepoint

At the gestational age of 24-28 weeks

Method of measurement

Pregnant women Records

Intervention groups

1

Description

Control group: Current supplementation during pregnancy (Iron, Folic acid, Multi-vitamin)

Category

Prevention

2

Description

Intervention group 1: Current supplementation during pregnancy (Iron, Folic acid, Multi-vitamin) + 1000 IU/d vitamin D

Category

Prevention

3

Description

Intervention group 2: Current supplementation during pregnancy (Iron, Folic acid, Multi-vitamin) + 2000 IU/d vitamin D

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarem Specialist Hospital

Full name of responsible person

Zahra Roostaei

Street address

Ekbatan Town, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti

University of Medical Sciences, School of Nutrition an

Full name of responsible person

Morteza Abdollahi

Street address

No.7, Hafezi St., Farahzadi Blvd., Shahrak Qods (Gharb), Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences, School of Nutrition an

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

National Nutrition and Food Technology Research Institute, Faculty of Nutrition Sciences and Food Te

Full name of responsible person

Soudabe Motamed

Position

PhD Student in Nutrition

Other areas of specialty/work

Street address

No.7, Hafezi St., Farahzadi Blvd., Shahrak Qods (Gharb), Tehran, Iran

City

Tehran

Postal code

198161957

Phone

+98 21 2237 6471

Fax

Email

s_motamed@sbmu.ac.ir; smotamed2010@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences, National Nutrition and Food Technology Research Inst

Full name of responsible person

Tirang Neyestani

Position

professor

Other areas of specialty/work

Street address

No. 7, Hafezi St., Farahzadi Blvd., Shahrak Qods (Gharb), Tehran, Iran

City

Tehran

Postal code

198161957

Phone

+98 21 2237 6471

Fax

+98 21 2237 6471

Email

neytr@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences, School of Nutrition Sciences and Food Technology, Na

Full name of responsible person

Soudabe Motamed

Position

PhD Student in Nutrition

Other areas of specialty/work

Street address

No.7, Hafezi St., Farahzadi Blvd., Shahrak Qods (Gharb), Tehran, Iran. Post code:1981619573

City

Tehran

Postal code

1981619573

Phone

+98 21 2209 7419

Fax

+98 21 2237 6471

Email

s_motamed@sbmu.ac.ir; smotamed2010@gmail.com

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