Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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 registeration
Secondary trial Id
no registeration
Registration date
empty

2

Registry name
no registeration
Secondary trial Id
no registeration
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
Getational 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

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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