

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the effects of different amounts of vitamin D supplementation on calcidiol, Anthropocentric status and body composition in lactation women with body mass index 25 and higher and their infants growth and frequency of visiting a doctor.

Protocol summary

Study aim

1. Comparison of changes in serum calcium diol, parathyroid, calcium and phosphorus levels between the three groups. 2. Comparison of changes in waist circumference, weight and body mass index between the three groups 3. Comparison of changes in body fat percentage, body weight (kg), fat mass (kg), visceral fat percentage, visceral fat mass (kg), and fat mass index between the three groups 4. Comparison of changes in height, weight and head circumference of infants in nursing mothers between the three groups 5. Comparison of different infections of the infant (tympanum-nose-eye-throat) between the three groups 6. Comparison of the frequency of visiting a doctor in the newborn between the three groups

Design

In this study, 90 mothers who are admitted to Dehkhoda Hospital for delivery are selected. Patients are randomly assigned to three interventions and control groups .

Settings and conduct

This study is a double-blind randomized clinical trial on mothers in Dehkhoda Hospital in Qazvin province.

Participants/Inclusion and exclusion criteria

All lactating mothers who have a BMI higher than 25, have no illnesses. They also express that they are breastfeeding their infants.

Intervention groups

90 nursing mothers are divided into three groups of 30. Group 1: Placebo Group II: (2000 IU / d) Third group: (4000 IU / D) high limit without risk of taking vitamin D (IOM).

Main outcome variables

Effect of vitamin D supplementation on serum Calcidiol, anthropometric measures and body composition in overweight or obese nursing mothers

General information

Reason for update

Unfortunately, in the trial registration some primary and secondary outcomes were written by mistake. So we want to revise them.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140413017254N6**
Registration date: **2018-11-04, 1397/08/13**
Registration timing: **prospective**

Last update: **2022-05-08, 1401/02/18**

Update count: **1**

Registration date

2018-11-04, 1397/08/13

Registrant information

Name

Gity Sotoude

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4293 3333

Email address

gsotodeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effects of different amounts of vitamin D supplementation on calcidiol, Anthropocentric status and body composition in lactation women with body mass index 25 and higher and their infants growth and frequency of visiting a doctor.

Public title
Comparison the effects of different amounts of vitamin D supplementation on calcidiol, Anthropocentric status and body composition in lactation women with body mass index 25 and higher and their infants growth and frequency of visiting a doctor.

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-49 Mother expresses feeding their infant Maternal delivery (between weeks 37 and 42) Body Mass Index (BMI): 25-39.9
Exclusion criteria:
Detected diseases such as cancer, digestive diseases, diabetes, high blood pressure, liver, kidney, autoimmune diseases, inflammation, thyroid Changing in diet over the past 3 months Regular supplementation of vitamin D (at least once a week or supplementing 50,000 units per month) or multivitamins (at least once a week) Smoking or any smoking, even once a week

Age
From **20 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Randomize permuted block randomization blocks Random unit: Individual
Randomized layers for stratified randomization: for age (under 30 and over 30) and body mass index (below 30 and higher than 30) Randomization Tool: random letters table

Blinding (investigator's opinion)
Double blinded

Blinding description
How to blind the study: Three types of supplements and

placebo will be provided with the same shape, color and size. A person who is not involved in the research team will be required to code for a variety of supplements, such as for the subjects and the researchers not be identified. At the end of the data collection, the codes of the supplements will be opened.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Central Building of Tehran University of Medical Sciences, Ghods st., Keshavarz Blv., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2018-10-01, 1397/07/09
Ethics committee reference number
IR.TUMS.VCR.REC.1397.429

Health conditions studied

1

Description of health condition studied
deficiency of vitamin D in lactating women
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
calcidiol
Timepoint
Before the intervention, After the intervention
Method of measurement
KIT

2

Description
PTH

Timepoint
Before the intervention, After the intervention
Method of measurement
KIT

3

Description
calcium
Timepoint
Before the intervention, After the intervention
Method of measurement
KIT

4

Description
phosphore
Timepoint
Before the intervention, After the intervention
Method of measurement
KIT

5

Description
Waist Circumference
Timepoint
Before the intervention, After the intervention
Method of measurement
meter-

6

Description
Height
Timepoint
Before the intervention, After the intervention
Method of measurement
meter

7

Description
weight
Timepoint
Before the intervention, After the intervention
Method of measurement
body impedance analysis Inbody270

8

Description
fat mass
Timepoint
Before the intervention, After the intervention
Method of measurement
body impedance analysis Inbody270

9

Description
fat free mass
Timepoint

Before the intervention, After the intervention
Method of measurement
body impedance analysis Inbody270

10

Description
body fat percentages
Timepoint
Before the intervention, After the intervention
Method of measurement
body impedance analysis Inbody270

11

Description
fat mass index
Timepoint
Before the intervention, After the intervention
Method of measurement
body impedance analysis Inbody270

12

Description
body mass index
Timepoint
Before the intervention, After the intervention
Method of measurement
body impedance analysis Inbody270

13

Description
relative fat mass
Timepoint
Before the intervention, After the intervention
Method of measurement
RFM index for women calculated as $76 - (20 \times \text{height} \times \text{WC in meters})$

Secondary outcomes

1

Description
Assessment of Neonatal Growth(height, head circumference and weight)
Timepoint
Before the intervention, After the intervention
Method of measurement
Data recorded in the case before the intervention and measurements of height, head circumference by meter and weight by scale at the end of the intervention

2

Description
frequency of visiting a doctor
Timepoint
Before the intervention, After the intervention
Method of measurement
doctor

Intervention groups

1

Description

Intervention group: Group 1: Vitamin D supplementation of 2000, IU/d in the form of micro nano capsules from the Nano hayat Pharmacy Company. A daily supplement of 2000 IU/d will be taken as a lunch capsule and a placebo with dinner.

Category

Treatment - Other

2

Description

Intervention group: The second group: two vitamins supplementation, 2000 IU/d, in the form of micro nano capsules from the nano-pharmaceutical company. A daily supplement of 2000IU/d will be consumed as a lunch capsule and a supplement of 2000IU/d.

Category

Treatment - Other

3

Description

The control group contains of 2000 IU/d vitamin D placebo in the form of micro nano from nano hayat pharmacy company. A daily dose of 2000 IU/d placebo will be taken as a lunch capsule and one placebo with dinner.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dehkhoda Superior Hospital

Full name of responsible person

Abolfazl Esfehany

Street address

North Ferdosy

City

Qazvin

Province

Qazvin

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Fax

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Email

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Web page address

http://dehkhodahospital.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

محمدعلی صحرانیان

Street address

Ghods St., Keshavarz Blvd., Central Organization of Tehran university of Medical Sciences

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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

Tehran University of Medical Sciences

Proportion provided by this source

80

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

Tehran University of Medical Sciences

Full name of responsible person

zohre gerveieeha

Position

phd student of nutrition course in tehran university

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

School of Nutrition, Tehran University Medical Sciences, Naderi St., Keshavarz Blvd., Tehran

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Province

Qazvin

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Gity Sotodeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

zohre gerveieeha

Position

phd candidate

Latest degree

Master

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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