

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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  $76 - (20 \text{ height} \times \text{WC in meters})$

## 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

##### Postal code

33413473

##### Phone

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##### Fax

+98 28 3334 1700

##### Email

info@dehkhodahospital.com

##### 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 صحرائیان

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

2188955698

##### Phone

+98 21 8163 3698

##### Email

Info\_snsd@tums.ac.ir

#### 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., Keshavar Blvd., Tehran

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qazvin

##### Province

Qazvin

##### Postal code

1439957181

**Phone**

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z.gerveiee1989@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**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**

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**Other areas of specialty/work**

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3414714493

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**Email**

z.gerveiee1989@gmail.com

## 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