

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison of 400 U Vs 600 U daily on Prevention of Osteopenia of Prematurity in preterm newborns with gestational age below 32 week

#### Protocol summary

##### Study aim

Evaluation and Comparison of mean serum Vitamin D, Total calcium, Phosphorus, Alkaline phosphatase and Clinical signs and Wrist radiographic changes in newborns receiving 400 Vs 600 U Vit D daily at the end of fifth weeks.

##### Design

Randomised, parallel group trial with blinded outcome assessment. Randomisation was centralised with Permuted block randomization

##### Settings and conduct

This study is randomized clinical trial conduct in Alzahra and Shahid beshti hospitals affiliated to Isfahan university of medical sciences. For first group and second group Vitamin D begin 400 u/day and 600 U/day respectively. Neonatologist prescribes drug. Fellow and statistical consultant have no any notice about dosage of drugs.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: - Newborns with GA below 32 W - Exclusive breastfeeding - Consent of parents for participation in study Exclusion criteria: - Vitamin D deficiency in mother - Perinatal asphyxia - IUGR - Pre Gestational and Gestational Diabetes mellitus

##### Intervention groups

For first group Vitamin D begin 400 u/day from seventh day of life. At fifth week of life Total calcium, Phosphorus, Alkaline phosphatase measure and if Alkaline phosphatase exceed from 1000 U/l radiography of wrist will be requested and radiologist report the graphy. fellow record clinical, laboratory and radiologic signs. for second group Vitamin D begin 400 u/day from seventh day of life. The other follow ups are similar to group 1.

##### Main outcome variables

serum Vitamin D, Total calcium, Phosphorus, Alkaline phosphatase, Clinical sign and Wrist radiographic change

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150423021910N7**

Registration date: **2021-01-14, 1399/10/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-14, 1399/10/25**

Update count: **0**

##### Registration date

2021-01-14, 1399/10/25

##### Registrant information

##### Name

Behzad Barekatin

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3261 6670

##### Email address

b\_barekatin@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-05-20, 1400/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of 400 U Vs 600 U daily on Prevention of Osteopenia of Prematurity in preterm newborns with gestational age below 32 week

## Public title

Appropriate Dose of Vitamin D on Prevention of Osteopenia of Prematurity

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Preterm newborns with Gestational age below 32w  
Exclusive breast feeding  
Use of milk fortifier 1 gr per 25 cc of breast milk  
Reach of full enteral feeding during first 10 days of life  
Discontinue of TPN during first 10 days of life  
Normal Vitamin D level in Mothers during Pregnancy

### Exclusion criteria:

Lack of perinatal Asphyxia  
Lack of IUGR  
Lack of Pre-Gestational and Gestational diabetes mellitus  
Lack of use of drugs interfere with Vitamin D metabolism

## Age

From **1 day** old to **35 days** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **108**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The infants were randomly allocated to either the 400 U or 600 U of Vitamin D by a method using permuted block randomization. Block size is 4. Randomization achieve through Random number table.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Neonatologist prescribe Vitamin D but Neonatology fellowship and Epidemiologist don't know which newborns receive 400 U or 600 U Vitamin D

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Ethics committee of Isfahan University of Medical Science

## Street address

Hezarjerib bolvar, Isfahan University of Medical Science

## City

Isfahan

## Province

Isfahan

## Postal code

8174673461

## Approval date

2020-12-31, 1399/10/11

## Ethics committee reference number

IR.MUI.MED.REC.1399.869

## Health conditions studied

### 1

#### Description of health condition studied

Osteopenia of prematurity

#### ICD-10 code

M81.9

#### ICD-10 code description

Osteoporosis, unspecified

## Primary outcomes

### 1

#### Description

Total serum calcium

#### Timepoint

Five weeks after intervention

#### Method of measurement

colorimetry

### 2

#### Description

Serum phosphorus

#### Timepoint

Five weeks after intervention

#### Method of measurement

colorimetry

### 3

#### Description

Serum alkaline phosphatase

#### Timepoint

Five weeks after intervention

#### Method of measurement

colorimetry

### 4

#### Description

Radiographic changes of wrist

#### Timepoint

Five weeks after intervention  
**Method of measurement**  
Report of Radiologist

## 5

**Description**  
Clinical symptoms of osteopenia  
**Timepoint**  
During study  
**Method of measurement**  
Clinical examination

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**  
Intervention group 1: Every 24 hours 25 drops equal to 1 cc of drop Vit D formulated in Alhavi Pharmacy company  
**Category**  
Prevention

### 2

**Description**  
Intervention group 2: Every 24 hours 37 drops equal to 1.5 cc of drop Vit D formulated in Alhavi Pharmacy company  
**Category**  
Prevention

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Alzahra Hospital  
**Full name of responsible person**  
Behzad Barekatin  
**Street address**  
Isfahan, Sofeh street  
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81746-75731  
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### 2

**Recruitment center**  
**Name of recruitment center**  
Shahid beheshti hospitals

**Full name of responsible person**  
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Isfahan, Felezi Bridge  
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## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Shaghayegh Haghjoo  
**Street address**  
Hezarjerib bolvar, Isfahan University of Medical Science  
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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**  
Esfahan University of Medical Sciences  
**Proportion provided by this source**  
100  
**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**  
Esfahan University of Medical Sciences  
**Full name of responsible person**

Behzad Barekatin

**Position**

Faculty members of Isfahan University of Medical Sciences

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for updating data

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**Latest degree**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more data

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available