

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Vitamin D Intake on Maternal of Delivery on Retinopathy of prematurity in Infants

#### Protocol summary

##### Study aim

Comparison of ROP incidence in preterm infants of mothers receiving and not receiving vitamin D

##### Design

A concealed, randomized, blinded, controlled clinical trial with a parallel group design of 93 mother, enrolled between January 2020 and September 2020

##### Settings and conduct

The design will be a one-blind clinical trial under the supervision of Mashhad University of Medical Sciences in 2020. Premature infants less than 34 weeks of gestation of mothers received vitamin D (the intervention group who received 50,000 units of vitamin D injections 72 hours ago) were compared with infants of mothers not use vitamin D, in terms of Retinopathy of prematurity(ROP). Diagnosis of ROP will be determined by an eye examination by a retina specialist. The level of vitamin D in the mother is measured after vitamin D is injected. A sample containing 1.5 cc of whole blood will be taken from the umbilical cord for measure of vitamin D. The prepared samples will be centrifuged at -20 ° C and send for laboratory evaluation. Vitamin D level will be measured by Elisa Reader RT2100c Made in Germany and Elisa Washing Machine .

##### Participants/Inclusion and exclusion criteria

Pregnant woman with gestational age less than 34 weeks will enter the study, Neonates with clear congenital anomaly, congenital infection ,death in the delivery room, Severe asphyxia, mothers with drug abuse will be excluded from the study.

##### Intervention groups

The intervention group received 50,000 units of vitamin D injections 72 hours before birth The control group received no medication.

##### Main outcome variables

with or without ROP

#### General information

##### Reason for update

Matching the date of approval of the ethics committee with the clinical trial and modifying the sample size

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110807007244N3**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **prospective**

Last update: **2022-05-24, 1401/03/03**

Update count: **1**

##### Registration date

2020-02-06, 1398/11/17

##### Registrant information

###### Name

Hassan Boskabadi

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 915 515 3987

###### Email address

boskabadih@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-20, 1398/12/01

##### Expected recruitment end date

2020-07-22, 1399/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effect of Vitamin D Intake on Maternal of Delivery on Retinopathy of prematurity in Infants

### Public title

Effect of Vitamin D Intake on Maternal of Delivery on Retinopathy of prematurity in Infants

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Pregnant woman with gestational age less than 34 weeks with symptoms of labor

#### Exclusion criteria:

congenital anomaly congenital infection death in the delivery room, Severe asphyxia mothers with drug abuse

### Age

No age limit

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **93**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization is based on simple random method using table of random numbers

### Blinding (investigator's opinion)

Single blinded

### Blinding description

The final outcome assessor i.e the researcher who will ultimately evaluate the children in terms of the outcome of the study(ROP), is blinded of group allocations

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad university of medical sciences

### Street address

NICU, Ghaem Hospital,Ahmadabad ST,Mashhad,Iran

### City

Mashhad

### Province

Razavi Khorasan

### Postal code

9138813944

### Approval date

2019-09-03, 1398/06/12

### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.526

## Health conditions studied

### 1

#### Description of health condition studied

Retinopathy of prematurity

#### ICD-10 code

H35.1

#### ICD-10 code description

Retinopathy of prematurity

## Primary outcomes

### 1

#### Description

present or unrepresented Retinopathy of prematurity

#### Timepoint

4 week after births

#### Method of measurement

retinal exam

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Pregnant mothers less than 34 weeks presenting with delivery symptoms while have Received 50000 Iu vitamin D

#### Category

Prevention

### 2

#### Description

Control group: Pregnant mothers less than 34 weeks presenting with delivery symptoms with routine care

#### Category

N/A

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Hassan Boskabadi

**Street address**

Ahmadabad ST

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91766-99199

**Phone**

+98 51 3878 7109

**Email**

boskabadih@mums.ac.ir

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Daneshgah ST

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91766-99199

**Phone**

+98 51 3840 0000

**Fax****Email**

Tafaghodim@mums.ac.ir

**Grant name**

Mashhad University of Medical Sciences

**Grant code / Reference number**

980131

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hassan Boskabadi

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Ahmadabad ST

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### Person responsible for scientific inquiries

#### Contact

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Mashhad University of Medical Sciences

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**Position**

Professor

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### Person responsible for updating data

#### Contact

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Mashhad University of Medical Sciences

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

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data of Vitamin D on ROP

**When the data will become available and for how long**

4 moth after end of research

**To whom data/document is available**

Mashhad University of Medical Sciences

**Under which criteria data/document could be used**

Ask a permission Mashhad University of Medical Sciences

**From where data/document is obtainable**

Mashhad University of Medical Sciences

**What processes are involved for a request to access data/document**

Ask a permission Mashhad University of Medical Sciences

**Comments**