

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vitamin D injection at birth on the incidence of retinopathy of prematurity

Protocol summary

Study aim

Incidence of ROP in premature infants receiving and not receiving vitamin D

Design

Clinical trial with control group, parallel groups, Triple blind , randomized with a sample size of 35 people in any groups from March 2021 to March 2022

Settings and conduct

The design will be a Triple blind clinical trial under the NICU of Ghaem hospital of Mashhad University of Medical Sciences . Infants are randomly divided into two groups. Premature infants less than 34 weeks of gestation received vitamin D who received 10,000 units of vitamin D injections at birth were compared with infants which not use vitamin D, in terms of Retinopathy of prematurity(ROP). Diagnosis of ROP will be determined by an eye examination by a retinologist. The baby's vitamin D level is measured before the vitamin D injection. 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

Inclusion criteria: Premature infants less than 34 weeks of gestation admitted to the neonatal intensive care unit
Conditions of absence: Obvious congenital anomaly, congenital infection, death in the delivery room, substance abuse by the mother

Intervention groups

Intervention groups: Premature infants less than 34 weeks of gestation admitted to the neonatal intensive care unit who receive 10,000 units of vitamin D, made by Caspian factory. Control group: Infants less than 34 weeks gestational age admitted to neonatal intensive care unit who do not receive vitamin D at birth.

Main outcome variables

Presence or absence of Retinopathy of prematurity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110807007244N9**

Registration date: **2022-07-17, 1401/04/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-17, 1401/04/26**

Update count: **0**

Registration date

2022-07-17, 1401/04/26

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

2022-06-22, 1401/04/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D injection at birth on the incidence of retinopathy of prematurity

Public title

The effect of vitamin D injection at birth on the incidence of retinal disorder of prematur infant

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Premature infants less than 34 weeks of gestational age admitted to the NICU

Exclusion criteria:

Overt congenital anomaly Death in delivery room Infants of drug-using mothers Mothers of Asthma

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: 35

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization will be used as a reliable randomization method that leads to a balanced allocation of individuals in treatment groups at the end of each block. For this purpose, using Random Allocation Software, a block randomization list with different sizes 4 or 6 is prepared, then according to the order of the contents of the blocks, which includes the group's name and unique identification code, each patient is assigned to one of the groups

Blinding (investigator's opinion)

Triple blinded

Blinding description

By admitted of newborn, the nurs accidentally opens one of the blocks and, without knowing the grouping, presents one of the numbers to a researcher who is aware of the type of group. The researcher injects 10000 IU from ampoule of vitamin D into the newborn of the intervention group. The infant will be followed up by the principal investigator who is unaware of the type of group, of the presence or absence of respiratory problem. Data entry in SPSS is done as groups A and B, and the data analyst is unaware from the intervention or control group.

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

2021-09-07, 1400/06/16

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.478

Health conditions studied

1

Description of health condition studied

Vitamin D and neonatal problems

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

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: remature infants less than 34 weeks of gestational age admitted to the Neonatal intensive care unit They will be injected once 10,000 units of vitamin D.

Category

Prevention

2**Description**

Control group: Premature infants less than 34 weeks of gestational age who have been admitted to the neonatal intensive care unit and have not received 10,000 units of vitamin D.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem Hospital

Full name of responsible person

boskabadi Hassan

Street address

Neonatal Intensive Care Unit, Pediatrics Dep, Ghaem Hospital, ahmadabad St.

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Email

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Majid ghayour mobarhan

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Vice Chancellor for Research and Technology ,
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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

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

Mashhad University of Medical Sciences

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Boskabadi Hassan

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City
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Province

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
The research team has no plans to publish the IPD
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