Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
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+98 915 515 3987
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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
Retinopaty 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

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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
Mohsen Tafaghodi

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Daneshgah ST

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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

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Person responsible for updating data

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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