Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of neonatal prognosis of vitamin D intake and no receive it at birth is premature infant

Protocol summary

Study aim
Determining the prognosis of infants consuming and not taking vitamin D at birth of premature infants
Design
Clinical trial with control group, parallel groups, single blind, randomized with a sample size of 50 people in any groups from March 2021 to March 2022
Settings and conduct
In the neonatal intensive care unite of the Ghaem hospital of Mashhad, the infants of the two groups are selected and the intervention group receives vitamin D. The researcher examines the infants without knowing the infants group and examines them for the presence or absence of neonatal complication.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Premature infants less than 34 weeks of gestation admitted to the neonatal intensive care unite Exclusion criteria: clear congenital anomaly, congenital infection, death in the delivery room, substance abuse by the mother of newborns
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
Need to ventilation, presence or absence of Intraventricular hemorrhage, length of hospital stay

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20110807007244N6**
Registration date: **2021-02-16, 1399/11/28**
Registration timing: **prospective**
Last update: **2021-02-16, 1399/11/28**
Update count: **0**
Registration date
2021-02-16, 1399/11/28

Registrant information
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Hassan Boskabadi
Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-19, 1399/12/01
Expected recruitment end date
2022-01-21, 1400/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of neonatal prognosis of vitamin D intake and no receive it at birth is premature infant

Public title
Comparison of neonatal prognosis of vitamin D intake and no receive it at birth is premature 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
From **1 day** old to **1 day** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

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)
Double 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
Ethics committee,3rd Floor, ghorashi bulding,Daneshgah St.

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2020-10-17, 1399/07/26

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.572

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
Duration of o2 therapy

Timepoint
28 day after birth

Method of measurement
تعداد ساعت

Secondary outcomes

1

Description
Duration of hospitalization

Timepoint
28 days old

Method of measurement
day

Intervention groups

1

Description
Intervention group: Premature 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Tafaghodi Mohsen
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Vice Chancellor for Research and Technology, Qureshi Building, University St.
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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
boskabadi Hassan
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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
There is no more information
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