# 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**
**Name**
Hassan Boskabadi
**Name of organization / entity**
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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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.
**City**
Mashhad
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Boskabadih@mums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Tafaghodi Mohsen
**Street address**
Vice Chancellor for Research and Technology, Qureshi Building, University St.
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Tafaghodim@mums.ac.ir
**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**
Pediatrics
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## Person responsible for scientific inquiries

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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