Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the incidence of respiratory distress syndrome in neonates of mothers receiving vitamin D with those who do not receive

Protocol summary

Study aim

The purpose is to compare the incidence of respiratory distress in first 72 postpartum in preterm infants of mothers receiving vitamin D with those who won't receive.

Design

A randomized controlled clinical trial with a parallel group design of 100 mother, enrolled between Tuesday, February 4, 2020 and Sunday, September 20, 2020

Settings and conduct

The study will be a clinical trial under the supervision of Mashhad University of Medical Sciences in 1398-1399. Preterm infants with gestational age of less than 34 weeks gestation of mothers who received vitamin D (the intervention group who received 50,000 units of vitamin D injections 72 hours before childbirth) with infants of mothers who did not received vitamin D would be compared in terms of incidence of RDS.

Participants/Inclusion and exclusion criteria

Inclusion criteria ; All singleton pregnant women with a gestational age of less than 34 weeks, at risk of preterm delivery Exclusion criteria; • Cardiovascular diseases (except for preeclampsia /eclampsia) • Asthma • History of certain illicit and prescription drugs(including narcotics, antiepileptic, non-steroid anti-inflammatory drugs, sedative-hypnotics, and tocolytics) • Multiple gestations

Intervention groups

The intervention group will receive 50,000 units of vitamin D injections 72 hours before childbirth and the control group won't receive any medication.

Main outcome variables

Neonatal respiratory distress reduction after prenatal maternal vitamin D injection

General information

Reason for update

Modification and updating of study data

Acronym

IRCT registration information

IRCT registration number: **IRCT20190814044529N1**
Registration date: **2020-01-21, 1398/11/01**
Registration timing: **prospective**

Last update: **2022-04-25, 1401/02/05**
Update count: **1**

Registration date

2020-01-21, 1398/11/01

Registrant information

Name

Mohammad Hosein Ataee Nakhaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3606 0413

Email address

ataeinmh971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-15, 1397/10/25

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

2020-02-04, 1398/11/15

Actual recruitment end date

2020-09-20, 1399/06/30

Trial completion date

2020-09-20, 1399/06/30

Scientific title

Comparison of the incidence of respiratory distress syndrome in neonates of mothers receiving vitamin D with those who do not receive

Public title
Effect of Vitamin D on neonatal respiratory distress
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All singleton pregnant women with a gestational age of less than 34 weeks, at risk of preterm delivery
Exclusion criteria:
Cardiovascular diseases (except for preeclampsia /eclampsia) Asthma History of certain illicit and prescription drugs(including narcotics, antiepileptic, non-steroid anti-inflammatory drugs, sedative-hypnotics, and tocolytics) Multiple gestations
Age
To **238 days** old
Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **175**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done based on simple random method using table of random numbers
Blinding (investigator's opinion)
Not blinded
Blinding description
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
Vice chancellor for research, Mashhad University of Medical Sciences, aneshgah St
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2016-08-17, 1395/05/27
Ethics committee reference number
IR.MUMS.fm.REC.1395.52

Health conditions studied

1

Description of health condition studied
neonatal respiratory distress
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Neonatal respiratory distress reduction
Timepoint
1-3 days after neonatal birth
Method of measurement
RDS will be diagnosed according to clinical criteria (tachypnea, subarachnoid retraction, grunting, groaning) and radiological criteria (volume reduction , Ground-glass, fading border of diaphragm and heart shadow).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group mothers will receive vitamin D injections(50,000 IU) 72 hours before childbirth.
Category
Treatment - Drugs

2

Description
Control group: No intervention including injection of Vitamin D will be done on mothers.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Hassan Boskabadi
Street address
1st Floor,Pediatric Ward, Ghaem Hospital, Ahmad

Abad Avenue,
City
Mashhad
Province
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Postal code
91766-99199
Phone
+98 51 3840 0000
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
1st Floor,Pediatric Ward, Ghaem Hospital, Ahmad Abad Avenue,
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Grant name
Grant code / Reference number
941645
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
Hasan Bosk abadi
Position
professore of pediatrics
Latest degree
Subspecialist
Other areas of specialty/work
neonatal perinatal medicine
Street address
1st Floor,Pediatric Ward, Ghaem Hospital, Ahmad Abad Avenue, Mashhad, Razavi Khorasan Province
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not 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