Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of the Effectiveness of Vitamin D Administration in the Treatment of Preterm Neonates with Respiratory Distress Syndrome

Protocol summary

Study aim
The aim of this study is the comparison of the effectiveness of vitamin D vs. placebo in preterm newborn with respiratory distress syndrome

Design
A phase 2, randomized, double-blind, placebo-controlled clinical trial with 3 parallel groups in 96 patients. The Randomization sequence will be generated by the free website at http://www.randomization.com.

Settings and conduct
96 preterm newborns between 28-34 weeks gestation with respiratory distress syndrome, referring to Neonatal Intensive Care Unit (NICU), Imam Khomeini Hospital, Ahvaz will be allocated in one of three groups based on blocked randomization. The Control group receives the standard care of RDS with placebo, Intervention group 1 receives vitamin D in the dose of 400 IU/Day with the standard care of RDS, Intervention group 2 receives vitamin D in the dose of 800 IU/Day with the standard care of RDS. The physician evaluates the clinical status of patients and the nurse is not aware of the intervention that patients receive. Three groups will be compared based on mortality rate and hospitalization duration on the first and last day of hospitalization.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Preterm newborn between 28-34 weeks gestation with respiratory distress syndrome; admitted to NICU Exclusion criteria: Neonates with neonatal sepsis; hypoxia; congenital disorders; feeding intolerance; newborn of diabetic mother

Intervention groups
The cases allocate into three groups, the control group receives the standard care of RDS with placebo, Intervention group 1 receives vitamin D in the dose of 400 IU/Day with the standard care of RDS, Intervention group 2 receives vitamin D in the dose of 800 IU/Day with the standard care of RDS.

Main outcome variables
Mortality rate; hospitalization duration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170307032933N4**
Registration date: **2021-06-22, 1400/04/01**
Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**
Update count: **0**

Registration date
2021-06-22, 1400/04/01

Registrant information

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Pedram Nazari

Name of organization / entity
Ahvaz Jundishapur 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
2021-06-28, 1400/04/07

Expected recruitment end date
2021-09-29, 1400/07/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effectiveness of Vitamin D Administration in the Treatment of Preterm Neonates with Respiratory Distress Syndrome

Public title
Effect of vitamin D in respiratory distress syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Preterm newborn between 28-34 weeks gestation Preterm newborn admitted to NICU Preterm newborn with the confirmed respiratory distress syndrome based on clinical and chest X-ray findings

Exclusion criteria:
Neonates with neonatal sepsis Neonates with hypoxia Neonates with congenital disorders Neonates with feeding intolerance Newborn of diabetic mother

Age
From **6 months** old to **8 months** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of patients into therapeutic or control groups will be done by Block Balanced Randomization (BBR) method by using blocks with size of 6. Individuals are the randomization unit. The Randomization sequence will be generated by using the free website at http://www.randomization.com. Allocation concealment will be done by assigning unique codes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Parents of premature infants know that their newborns are enrolled in an investigation that is aimed to evaluate the vitamin D effect on the respiratory distress syndrome, but they are not informed that they receive placebo or vitamin D. The physician who evaluates the clinical status of patients and the nurse are not aware of the intervention that patients receive. The drug and placebo in each group are exactly in the same form and packages. The packages are distinguished only by mentioning the number and the list of numbers will be at the disposal of the statistical consultant and then the data will be analyzed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Golestan Hospital

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

City
Ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2021-06-01, 1400/03/11

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1400.050

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrome of newborn

ICD-10 code
P22.0

ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Mortality rate

Timepoint
Within admission period

Method of measurement
Reports of nurses or physicians

Secondary outcomes

1

Description
Hospitalization duration

Timepoint
The first day and the last day of the patient's hospitalization

Method of measurement
Patient record

Intervention groups

1

Description
Intervention group 1: Daily 400 IU (1 cc) of vitamin D Drop (1000 IU, Alhavi company, Iran) for three weeks is administrated.
Category
Treatment - Drugs

2

Description
Intervention group 2: Daily 800 IU (1 cc) of vitamin D Drop (2000 IU, Alhavi company, Iran) for three weeks is administrated.
Category
Treatment - Drugs

3

Description
Control group: Daily 1 cc of placebo drop (Alhavi company, Iran) for three weeks is administrated.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neonatal Intensive Care Unit of Imam Khomeini Hospital
Full name of responsible person
Arash Malekian
Street address
Imam Khomeini Hospital, Azadegan Street, Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadimoghadam
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Vice Chancellor for research and technology of Ahvaz Jundishapur University of Medical Sciences, Daneshgahi Settlements, Ahvaz
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Arash Malakian
Position
Associate professor
Latest degree
Subspecialist
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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
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available