

# 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

##### Name

Pedram Nazari

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3311 7705

##### Email address

nazari.p@ajums.ac.ir

##### 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

Khuzestan

##### 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

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6135715794

##### Phone

+98 61 3311 7705

##### Email

malekianarash@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mehdi Ahmadimoghadam

##### Street address

Vice Chancellor for research and technology of Ahvaz

Jundishapur University of Medical Sciences,  
Daneshgahi Settlements, Ahvaz

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

1579461357

##### Phone

+98 61 4355 4063

##### Email

ahmadi-m@ajums.ac.ir

##### 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

##### Other areas of specialty/work

Pediatrics

##### Street address

Department of Neonatology, Imam Khomeini Hospital,  
Azadegan St

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0098 61 3367543

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malekianarash@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Phone**

0098 61 3367543

**Email**

jamshidsafdarian@yahoo.com

**Web page address****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

**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Jamshid Safdarian

**Position**

Neonatology fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics