# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of Extubation Failure Rates in Premature infants Receiving high Versus low Pressure nCPAP at Afzalipour Hospital in 2026: A Clinical Trial.

## Protocol summary

**Study aim**

The Primary Objective is to compare the rate of Extubation Failure in Premature Infants Receiving High-Pressure (8–10 $cmH_2O$) versus low-Pressure (6–8 $cmH_2O$) nCPAP.

**Design**

A randomized, parallel-group clinical trial with blinding of outcome assessor and statistician. Randomization will be performed using block randomization (with block sizes of 4 or 6), and allocation concealment will be achieved using sequentially numbered, sealed, opaque envelopes (SNOSE).

**Settings and conduct**

A randomized clinical trial on premature infants comparing extubation failure rates between two groups receiving high-pressure (8–10 $cmH_2O$) versus low-pressure (6–8 $cmH_2O$) nCPAP. Primary outcome: Extubation failure within 7 days. Study setting: NICU of Afzalipour Hospital, Kerman.

**Participants/Inclusion and exclusion criteria**

Inclusion: Preterm infants with gestational age less than 37 weeks, hospitalized in the NICU, receiving invasive mechanical ventilation, candidates for first-time Extubation, with parental informed consent. Exclusion: Parental refusal, congenital or genetic anomalies affecting respiration, lack of ongoing intensive care provision.

**Intervention groups**

Group 1: Receives high-pressure nCPAP (8–10 $cmH_2O$) - Intervention Group. Group 2: Receives low/standard-pressure nCPAP (6–8 $cmH_2O$) - Control Group. Both groups receive surfactant and are followed for 7 days for extubation failure.

**Main outcome variables**

Primary Outcome: Extubation failure within 7 days post-extubation. Definition: Presence of at least one of the following criteria in infants receiving maximum allowable nCPAP pressure: 1) $FiO_2$ requirement ≥ 0.2 above pre-extubation level, 2) pH < 7.20 and $PCO_2$ > 60 mmHg, 3) Recurrent apnea (more than one episode requiring PPV in 24 hours or ≥ 6 episodes requiring stimulation in 6 hours), 4) Urgent need for re-intubation.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20211218053444N4**
Registration date: **2026-07-06, 1405/04/15**
Registration timing: **prospective**

Last update: **2026-07-06, 1405/04/15**
Update count: **0**

**Registration date**

2026-07-06, 1405/04/15

**Registrant information**

**Name**

Zahra Jamali

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 34 3132 8198

**Email address**

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-07-22, 1405/04/31

**Expected recruitment end date**

2027-01-20, 1405/10/30

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of Extubation Failure Rates in Premature infants Receiving high Versus low Pressure nCPAP at Afzalipour Hospital in 2026: A Clinical Trial.

**Public title**
Comparison of the Effect of high Versus low Pressure nCPAP on Extubation Success rate in Premature Infants
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Less than 37 Completed Weeks of Gestation (preterm infant) Receiving Invasive Mechanical Ventilation (Via Endotracheal Tube) in the NICU Being extubated for the first time (no History of previous extubation). Obtaining written Informed Consent from Parents after full Explanation of the Procedures, Significance, and Outcomes of the study.
**Exclusion criteria:**
Parental Refusal Congenital or Genetic anomalies Affecting Respiration Lack of Ongoing Intensive Care Provision
**Age**
From **8 months** old to **8 months** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **199**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization will be performed using block randomization with variable block sizes (4 or 6). The randomization sequence will be generated using statistical software and placed in sequentially numbered, sealed, opaque envelopes (SNOSE). The envelopes will remain concealed from the treating team and investigators until the infant is enrolled and prepared for extubation. Envelope opening and infant allocation will be performed by an individual independent of the treating team. This method was chosen due to the limited sample size (fewer than 100 participants per group) and the need to maintain balanced sample sizes between the two groups.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Blinding will be performed for the outcome assessor and statistician. The outcome assessor (a neonatal subspecialist or trained nurse) and the statistician will be blinded to the intervention groups. The treating team and parents will not be blinded due to the nature of the intervention. Allocation concealment will be achieved using sequentially numbered, sealed, opaque envelopes (SNOSE).
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of Afzalipour Hospital-Kerman University of Medical Sciences
**Street address**
Emam Blv., Hospital Afzalipour
**City**
Kerman
**Province**
Kerman
**Postal code**
7619813159
**Approval date**
2026-05-02, 1405/02/12
**Ethics committee reference number**
IR.KMU.AH.REC.1405.014

## Health conditions studied

### 1

**Description of health condition studied**
Extubation Failure in Premature Infants
**ICD-10 code**
P28.5
**ICD-10 code description**
Respiratory failure of newborn

## Primary outcomes

### 1

**Description**
Extubation Failure within 7 days post-Extubation, Defined as Impaired Oxygenation ($FiO_2 \geq 0.2$ above Pre-extubation level), Respiratory Acidosis ($pH < 7.20$ and $PCO_2 > 60$ mmHg), Recurrent Apnea, or Urgent need for re-Intubation.
**Timepoint**
Baseline Variables Measured before Extubation. Intervention Initiated immediately after Extubation (hour

zero). Daily Assessment of Primary Outcome (Extubation failure) for 7 days (168 hours). Duration of Ventilation and Hospitalization Recorded throughout the study period. Mortality and Re-intubation Requirement recorded during Follow-up. Final data Analysis performed at the end of day 7.

**Method of measurement**

Baseline Variables Measured before extubation. Intervention initiated immediately after extubation (hour zero). Daily Assessment of Primary Outcome (Extubation Failure) for 7 days (168 hours). Duration of Ventilation and Hospitalization Recorded throughout the study period. Mortality and re-intubation Requirement recorded during follow-up. Final data Analysis performed at the end of day 7.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Receives high-pressure nCPAP (8–10 $cmH_2O$) immediately after extubation. Infants in this group receive surfactant (Beraksurf) via a feeding tube with PPV assistance over 2–3 minutes following intubation. After clinical readiness is confirmed, they are extubated and immediately placed on nCPAP at 8–10 $cmH_2O$. The primary outcome (extubation failure) is assessed for 7 days (168 hours).

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Receives low/standard-pressure nCPAP (6–8 $cmH_2O$) immediately after extubation. Infants in this group, like the intervention group, receive surfactant (Beraksurf) via a feeding tube with PPV assistance over 2–3 minutes following intubation. After clinical readiness is confirmed, they are extubated and immediately placed on nCPAP at 6–8 $cmH_2O$ (standard pressure). The primary outcome (extubation failure) is assessed for 7 days (168 hours).

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Afzalipur Kerman Hospital

**Full name of responsible person**
Zahra Jamali

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Imam Khomeini Boulevard, Next to Bahnar University

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Kerman University of Medical Sciences

**Full name of responsible person**
Hamid Sharifi

**Street address**
Ebn-e-Sina St., Jahad Blvd., Kerman University of Medical Sciences

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sharifihami@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Kerman 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**
Kerman University of Medical Sciences

**Full name of responsible person**
Zahra Jamali

**Position**

Assistant 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)**
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