

# Comparison of X-Breathe HFNC Neo™ high-flow nasal cannula versus standard continuous positive airway pressure in late preterm neonates with respiratory distress

<b>Submission date</b> 10/04/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/04/2025	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/04/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Respiratory distress is a common challenge in neonates. Among non-invasive modalities, High-Flow Nasal Cannula (HFNC) and Continuous Positive Airway Pressure (CPAP) are widely used. XBreatheNeo™ HFNC is designed to deliver low-flow oxygen specifically to neonates. This study compares the performance of XBreatheNeo™ HFNC with standard CPAP in late preterm and term neonates with respiratory distress.

### Who can participate?

Neonates diagnosed with respiratory distress syndrome with a gestational age of more than 28 weeks, birth weight exceeding 1500 grams admitted to the Neonatal Intensive Care Unit (NICU) at Bandung Kiwari General Hospital from October to December 2022

### What does the study involve?

Participants were randomly assigned to use either the HFNC or CPAP device. The HFNC started with an airflow of 5 liters per minute, adjusted to maintain stable oxygen levels, and reduced when conditions improved. The CPAP began with a pressure of 7 cmH<sub>2</sub>O, which was gradually decreased as the newborns' breathing stabilized. All procedures were overseen by a neonatologist and an intensivist.

### What are the possible benefits and risks of participating?

All treatments of the patients will be fully covered by the researchers. Patients will get compensation if unwanted events occur during the study.

The possible risks during participation are desaturation, hemodynamic changes, or oxygenation failure

### Where is the study run from?

The Bandung Kiwari General Hospital, Bandung, West Java, Indonesia

When is the study starting and how long is it expected to run for?  
September 2022 until December 2022

Who is funding the study?

1. Xirka Dama Persada, Ltd
2. Indonesia Higher Education Ministry Research Grant Kedaireka 2022

Who is the main contact?

Dr Reza Widiyanto Sudjud, reza.widiyanto.sudjud@unpad.ac.id

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Dr Reza Widiyanto Sudjud

### Contact details

Jalan Pasteur no.38

Bandung

Indonesia

40161

+62 813-2000-3010

reza.widiyanto.sudjud@unpad.ac.id

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Performance of X-Breathe HFNC Neo™ oxygenation in late preterm neonates with respiratory distress

### Study objectives

XBreatheNeo™ HFNC demonstrates excellent performance as a respiratory support device and is equally effective as standard CPAP in late preterm and term neonates

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 19/08/2022, Research Ethic Review Committee of Dr. Hasan Sadikin General Hospital (Jalan Pasteur no.38, Bandung, 40161, Indonesia; +62 22 2034953; rsup@rshs.web.id), ref: LB. 02.01/X.6.5/288/2022

**Study design**

Single-center interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment, Safety, Efficacy

**Participant information sheet**

See study outputs table

**Health condition(s) or problem(s) studied**

Respiratory distress

**Interventions**

The interventions in this study include the XBreathe Neo™ High-Flow Nasal Cannula (HFNC) and the standard Continuous Positive Airway Pressure (CPAP) device routinely used at Bandung Kiwari General Hospital. The study involves neonates admitted to the Neonatal Intensive Care Unit (NICU) of Bandung Kiwari General Hospital from October to December 2022. Patients were recruited through consecutive sampling. The main goal of the current clinical trial is to test the efficacy and safety of a new product produced in Indonesia, namely XBreathe Neo™HFNC. As a comparison, CPAP was applied in the control arm. Patients were randomized to receive HFNC or CPAP using a simple computer-generated randomization based on their identification numbers.

**Procedure****A. High-Flow Nasal Cannula (HFNC)**

The initial HFNC setting consisted of an airflow rate of 5 liters per minute (LPM). The fraction of inspired oxygen (FiO<sub>2</sub>) was adjusted to maintain peripheral oxygen saturation (SpO<sub>2</sub>) between 91% and 95%. Airflow was increased by 1 LPM, up to a maximum of 7 LPM, if any of the following criteria were met:

1. An increase in FiO<sub>2</sub> by 10% above the initial FiO<sub>2</sub>.
2. An increase in the Downe Score by 1 point from baseline.

Airflow was reduced by 0.5 to 1.0 LPM once all of the following conditions were met:

1. FiO<sub>2</sub> < 30%
2. Stable SpO<sub>2</sub> between 91% and 95%

3. Absence of respiratory distress (Downe Score < 4)

Once these parameters remained stable, neonates were gradually weaned from HFNC.

#### **B. Continuous Positive Airway Pressure (CPAP)**

The initial Positive End-Expiratory Pressure (PEEP) was set to 7 cmH<sub>2</sub>O. PEEP was reduced stepwise by 1 cmH<sub>2</sub>O when all of the following conditions were met:

1. Downe Score < 4
2. SpO<sub>2</sub> maintained between 91% and 95% with FiO<sub>2</sub> < 30%
3. Respiratory rate within the normal range for neonatal age
4. Minimal or no episodes of apnea, bradycardia, or desaturation

Who: All procedures were delivered by a neonatologist and an intensivist.

#### **Intervention Type**

Device

#### **Pharmaceutical study type(s)**

Not Applicable

#### **Phase**

Phase I

#### **Drug/device/biological/vaccine name(s)**

XBreatheNeo™ High Flow Nasal Cannula, Standard Continuous Positive Airway Pressure

#### **Primary outcome measure**

The following primary outcome measures were recorded every 15 minutes during the first 3 hours, and subsequently every 2 hours for a total observation period of 48 hours:

1. Peripheral capillary oxygen saturation (SpO<sub>2</sub>) measured using the sensors integrated into the multiparameter patient monitors available in the NICU
2. Fraction of inspired oxygen (FiO<sub>2</sub>) measured using data recorded directly from the CPAP or HFNC devices
3. Respiratory rate (RR) measured using the sensors integrated into the multiparameter patient monitors available in the NICU
4. Heart rate (HR) measured using the sensors integrated into the multiparameter patient monitors available in the NICU
5. Hypoxia in clinically respiratory distressed neonates measured using Downe's Score based on clinical findings

#### **Secondary outcome measures**

Adverse events measured using observations during the study duration of 48 hours

#### **Overall study start date**

19/08/2022

#### **Completion date**

31/12/2022

## **Eligibility**

#### **Key inclusion criteria**

1. Neonates with a gestational age of more than 28 weeks
2. Birth weight exceeding 1500 grams
3. Admitted to the Neonatal Intensive Care Unit (NICU) at Bandung Kiwari General Hospital from October to December 2022
4. Diagnosed with respiratory distress syndrome (characterized by tachypnea, chest wall retraction, moaning, and Dawne Score > 4)

**Participant type(s)**

Patient

**Age group**

Neonate

**Lower age limit**

0 Days

**Upper age limit**

0 Days

**Sex**

Both

**Target number of participants**

22

**Total final enrolment**

22

**Key exclusion criteria**

1. Had already experienced severe respiratory distress
2. Were likely to develop respiratory failure requiring invasive ventilation
3. Declined to participate in the study

**Date of first enrolment**

01/10/2022

**Date of final enrolment**

31/12/2022

**Locations****Countries of recruitment**

Indonesia

**Study participating centre**

**Bandung Kiwari General Hospital**

Jl. Raya Kopo No.311, RT.03/RW.05, Situsaeur, Kec. Bojongloa Kidul

Bandung  
Indonesia  
40233

## Sponsor information

### Organisation

Dr. Hasan Sadikin General Hospital

### Sponsor details

Jalan Pasteur no.38  
Bandung  
Indonesia  
40161  
+62222034953  
rsup@rshs.web.id

### Sponsor type

Hospital/treatment centre

### Website

<https://www.rshs.or.id>

### ROR

<https://ror.org/003392690>

## Funder(s)

### Funder type

Industry

### Funder Name

PT Xirka Dama Persada

### Funder Name

Indonesia Higher Education Ministry

## Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

### Intention to publish date

20/06/2025

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to privacy of the participants

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		22/03/2022	22/04/2025	No	Yes
<a href="#">Protocol file</a>			22/04/2025	No	No
<a href="#">Statistical Analysis Plan</a>			22/04/2025	No	No