

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

Submission date 10/04/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/04/2025	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/04/2025	Condition category 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 cmH₂O, 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

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Treatment, Safety, Efficacy

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 (FiO₂) was adjusted to maintain peripheral oxygen saturation (SpO₂) 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 FiO₂ by 10% above the initial FiO₂.
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. FiO₂ < 30%
2. Stable SpO₂ 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 cmH₂O. PEEP was reduced stepwise by 1 cmH₂O when all of the following conditions were met:

1. Downe Score < 4
2. SpO₂ maintained between 91% and 95% with FiO₂ < 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

Phase

Phase I

Drug/device/biological/vaccine name(s)

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

Primary outcome(s)

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 (SpO₂) measured using the sensors integrated into the multiparameter patient monitors available in the NICU
2. Fraction of inspired oxygen (FiO₂) 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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Lower age limit

0 days

Upper age limit

0 days

Sex

All

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

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

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?
Participant information sheet		22/03/2022	22/04/2025	No	Yes
Protocol file			22/04/2025	No	No
Statistical Analysis Plan			22/04/2025	No	No