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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

Registration date
23/04/2025

Overall study status
Completed

Last Edited
22/04/2025

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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_2O, 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?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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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_2) was adjusted to maintain peripheral oxygen saturation (SpO_2) 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_2 by 10% above the initial FiO_2.
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. $FiO_2 < 30\%$
2. Stable SpO_2 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_2O. PEEP was reduced stepwise by 1 cmH_2O when all of the following conditions were met:
1. Downe Score < 4
2. SpO_2 maintained between 91% and 95% with FiO_2 < 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_2) measured using the sensors integrated into the multiparameter patient monitors available in the NICU
2. Fraction of inspired oxygen (FiO_2) 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

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Sponsor information

Organisation
Dr. Hasan Sadikin General Hospital

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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?
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