ISRCTN68812324 https://doi.org/10.1186/ISRCTN68812324

Clinical trial of noninvasive ventilator XVENT XVM20 FrontlinerTM

Submission date
03/07/2025

Recruitment status
No longer recruiting

Registration date
13/07/2025

Overall study status
Completed

Last Edited
11/07/2025

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Respiratory insufficiency is a condition where the lungs cannot adequately exchange gases. Non-invasive respiratory support plays a critical role in managing respiratory insufficiency, helping to reduce the need for invasive mechanical ventilation and its associated complications. In light of increasing clinical demands, especially in resource-limited settings, the development of reliable and cost-effective ventilator technologies is critical. The XVENT XVM20 FrontlinerTM is a domestically designed, non-invasive ventilator supporting both CPAP and BiPAP modes, produced by Xirka Dama Persada Ltd., Indonesia. The aim of this study is to test the effectiveness and safety of this device.

Who can participate:
Patients aged over 18 years with decreased peripheral oxygen saturation (less than 93%) and a respiratory rate between 28 and 30 breaths per minute

What does the study involve?
Patients were randomly assigned to receive either CPAP or BiPAP therapy using the XVENT XVM20 FrontlinerTM. Peripheral oxygen saturation, respiratory rate, heartbeat rate and blood pressure were monitored through attached sensors and recorded at baseline, every 15 minutes during 3 hours of observation, and every 2 hours in the next 51 hours. Patients' comfort was also observed. Device-related parameters, including electrical, noise, temperature, pressure, and inspiratory/expiratory time stability, were also recorded at baseline, every 15 minutes during 3 hours of observation, and every 2 hours in the next 51 hours.

What are the possible benefits and risks of participating
Benefits:
Participants will receive free medical treatment for hypoxia and may be provided with financial compensation.
Potential risks:
1. Treatment failure, in which oxygenation does not improve within 2–3 hours of therapy initiation.
2. Discomfort or agitation experienced during the use of the non-invasive ventilation device.

Where is the study run from?
Advent Hospital (Indonesia)

When is the study starting and how long is it expected to run for?
July 2020 to October 2020

Who is funding the study?
This study was supported by Universitas Padjadjaran internal grant. Additional support was provided by Xirka Darma Persada Ltd. for equipment and technical resources. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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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
Assessing the efficacy of X-VENT ventilation: a performance comparison with continuous positive airway pressure and bilevel positive airway pressure modes

Study objectives
1. To evaluate the effect of the XVENT™ XMV20 Frontliner in continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) modes on:
1.1. Patient oxygenation levels (SpO_2)
1.2. Respiratory rate
1.3. Blood pressure
2. To assess the pressure stability of the device during use:
2.1. Positive end expiratory pressure (PEEP) in CPAP mode
2.2. Inhalation positive airway pressure (IPAP) and exhalation positive airway pressure (EPAP) in BiPAP mode
2.3. EPAP and IPAP duration in BiPAP mode
3. To evaluate patient comfort during the use of CPAP and BiPAP modes.
4. To assess the operational stability, noise level, and electrical performance of the XVENT™ XMV20 Frontliner during patient use in both CPAP and BiPAP modes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/07/2020, Research Ethics Review Committee of Dr. Hasan Sadikin General Hospital (Jalan Pasteur no.38, Bandung, 40161, Indonesia; +62 (0)222034953; rsup@rshs.web.id), ref: LB. 02.01/X.6.5/198/2020

Study design
Single-blind equivalence two-arm parallel-group interventional study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
https://drive.google.com/file/d/1WDcwe2xgvKOjngdYVsX0dnlheoKUSK91/view?usp=drive_link

Health condition(s) or problem(s) studied
Desaturation (SpO_2 <95%) not requiring invasive ventilation

Interventions
Initially, the XVENT™ XMV20 Frontliner was connected to an oxygen source with a flow rate of 15 L/min. A nasal mask was then applied to the patient, ensuring a tight yet comfortable fit without air leakage. The CPAP and BiPAP settings were subsequently configured as follows:

1. Continuous Positive Airway Pressure (CPAP)
Initial pressure was set at 5 cmH2O and FiO2 was adjusted to maintain SpO2 >95%.

2. Bi-level Positive Airway Pressure (BiPAP)
The Inspiratory Positive Airway Pressure (IPAP) was set to 10 cmH_2O, and the Expiratory Positive Airway Pressure (EPAP) was set to 5 cmH_2O. The inspiratory-to-expiratory (I:E) ratio was configured at 1:2. The inspiratory time was set to 1.7 seconds, and the expiratory time to 3.5 seconds.

Patients were randomly assigned to receive either CPAP or BiPAP therapy using computer-generated randomization based on hospital registration numbers, as performed by a statistician. An equal allocation ratio of 1:1 was applied to ensure balanced group sizes between the two treatment arms.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
XVENT XVM20 Frontliner

Primary outcome measure
1. Peripheral oxygen saturation (SpO2) measured using a finger pulse oximeter at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours
2. Respiratory rate measured using XVENT XVM20 FrontlinerTM flow sensor, displayed on the device’s monitor at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours

3. Blood pressure measured using an external pressure sensor at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours
4. Heartbeat rate measured using external pulse sensor at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours
5. Patient comfort assessed using a 5-point Agitation Numeric Scale, where a score of 1 indicated very uncomfortable and agitated, and a score of 5 indicated very comfortable and relaxed at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours
6. Adverse events recorded during the experiment and 1 day after the experiment

Secondary outcome measures
1. Electrical stability, assessed by observing for any unexpected power loss or shutdown during device operation at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours
2. Noise stability, evaluated based on whether the device generates excessive or abnormal noise during use at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours
3. Temperature stability, determined by monitoring for any sudden increase in device temperature due to inadequate heat dissipation at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours
4. Pressure delivery stability, assessed by verifying whether the device consistently delivers the desired CPAP/EPAP and IPAP pressures over time at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours
5. Inspiratory and expiratory time stability, evaluated by checking whether the device accurately delivers IPAP and EPAP according to the preset inspiratory and expiratory durations at baseline, every 15 minutes during the first 3 hours and every 2 hours for the subsequent 51 hours, resulting in a total observation period of 54 hours

Overall study start date
01/07/2020

Completion date
20/10/2020

Eligibility

Key inclusion criteria
1. Decreased oxygen saturation (SpO_2 <95%)
2. Respiratory rate 28 - 30 times per minute

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Moderate to severe impaired consciousness (Glasgow Coma Scale score < 13)
2. Severe tachycardia (heart rate >120 beats per minute)
3. Respiratory failure requiring invasive ventilation and admission to the Intensive Care Unit (ICU)

Date of first enrolment
01/07/2020

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
Indonesia

Study participating centre
Advent Hospital
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Sponsor information

Organisation
Xirka Dama Persada Ltd

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Sponsor type
Industry

Website
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Funder(s)

Funder type
University/education

Funder Name
Universitas Padjadjaran

Alternative Name(s)
Padjadjaran University, UNPAD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
06/07/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study are not expected to be made available due to patient privacy concerns and institutional data protection policies.

IPD sharing plan summary
Not expected to be made available