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Distinct physiological effects of high-flow nasal cannula, helmet CPAP, and their combination in acute hypoxemic respiratory failure

Submission date 07/05/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/06/2026	**Overall study status** Completed	
Last Edited 20/07/2026	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

OSF preregistration
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Study information

Scientific Title
Physiological comparison of high-flow nasal cannula, helmet CPAP and their combination in acute hypoxemic respiratory failure: a crossover physiological study

Acronym
HFNC-HELMET Study

Study objectives
To compare the physiological effects of high-flow nasal cannula (HFNC), helmet CPAP (H-CPAP), and their combination (HFNC+CPAP) on inspiratory effort, respiratory mechanics, and gas exchange in ICU patients with acute hypoxemic respiratory failure

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/02/2024, Ethics Committee for Clinical Trials – Province of Trento (Comitato Etico per la Sperimentazione Clinica – Provincia di Trento) (Via Gilli 4, Trento, 38121, Italy; +39 0461 904111; comitato.etico@apss.tn.it), ref: #4638-26/02/2024

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Acute hypoxemic respiratory failure in ICU patients

Interventions
The study was designed as a randomized crossover physiological investigation.
The sequence of the three interventions (HFNC, Helmet CPAP, HFNC+CPAP) was randomized using a computer-generated randomization sequence created with Random.org. Allocation was generated before study procedures and applied sequentially for each enrolled patient.

Enrolled ICU patients undergo three interventions in random order:

High-flow nasal cannula (HFNC) at 50 L/min;
Helmet CPAP (H-CPAP) with PEEP 8 cmH2O and total flow 80 L/min;
Combined HFNC+CPAP with HFNC delivered inside the helmet.

Each intervention lasts 30 minutes. Inspiratory effort, respiratory mechanics, ventilatory pattern, and gas exchange are measured during each phase.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
High-flow nasal cannula (HFNC), Helmet CPAP (H-CPAP), combined HFNC+CPAP support

Primary outcome(s)
1. Inspiratory effort measured using Esophageal pressure swing (ΔPes) and simplified esophageal pressure–time product per minute (sPTPes/min) measured using esophageal manometry, at each 30-minute intervention phase (HFNC, H-CPAP, HFNC+CPAP)

Key secondary outcome(s)
1. Gas exchange and respiratory mechanics measured using PaO_2/FiO_2 ratio, venous admixture, $PaCO_2$, respiratory rate, tidal volume, minute ventilation, dynamic transpulmonary driving pressure (ΔPL), and dynamic lung compliance, at the final 5 minutes of each 30-minute intervention phase.

2. Ventilatory load measured using the respiratory rate, minute ventilation (Ve), and Ve corrected for $PaCO_2$ at each 30-minute intervention phase

3. Oxygenation measured using PaO_2/FiO_2 ratio and venous admixture obtained from arterial blood gas analysis, at the final 5 minutes of each intervention phase

4. Pneumatic performance of PEEP valves measured using airway pressure swing (ΔPaw) and correlation between ΔPaw and ΔPes using flow-dependent and flow-independent PEEP valves, at H-CPAP and HFNC+CPAP phases

5. Non-invasive ventilation (NIV) failure measured using data on the need for endotracheal intubation after non-invasive respiratory support, at within 48 hours after study completion

6. Patient comfort and dyspnea measured using the Borg dyspnea and discomfort scales, at each intervention phase

Completion date
01/01/2025

Eligibility

Key inclusion criteria
1. Adult ICU patients with acute hypoxemic respiratory failure requiring supplemental oxygen therapy to maintain PaO_2 >60 mmHg or SpO_2 >90%, $PaCO_2$ <45 mmHg
2. Respiratory rate >25 breaths/min
3. Acute onset of symptoms within 7 days of hospital admission
4. Age >18 years

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
18

Key exclusion criteria
1. Asthma or COPD exacerbation
2. Cardiogenic pulmonary edema
3. Chronic neuromuscular disease
4. Pulmonary embolism
5. Pregnancy

Date of first enrolment
08/03/2024

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Ospedale Santa Chiara

ROR
https://ror.org/007x5wz81

Funder(s)

Funder type

Funder Name
Ministero della Salute

Alternative Name(s)
Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			13/05/2026	No	No
Participant information sheet	Italian version 1.0	01/02/2023	13/05/2026	No	Yes
Protocol file	Italian	26/04/2023	07/05/2026	No	No
Protocol file	English	26/04/2023	20/07/2026	No	No
Statistical Analysis Plan			13/05/2026	No	No