High Flow Nasal Oxygen For Hypercapnic, Acidotic Exacerbation Chronic Obstructive Pulmonary Disease. (HicaP)

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To assess the feasibility of a larger study comparing HFNO with NIV as first line treatment in hypercapnic, acidotic AECOPD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON53264

Source
ToetsingOnline

Brief title
HFNO in COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: Stichting bevordering onderzoek franciscus

Intervention

Keyword: COPD, High Flow Nasal Oxygen, non-invasive ventiliation

Outcome measures

Primary outcome

Feasibility: screening rate, inclusion rate, feasibility as qualified by staff

and nurses.

Secondary outcome

• Treatment failure:

* Treatment with another modality (HFNO or NIV) (cross-over)

* Invasive mechanical ventilation

* Death

o Reason of failure: clinical deterioration or failure to improve (as described

in section 3.5), / treatment intolerance / other

o Expression of failure: worsening of pH, PaCO2, respiratory rate,

consciousness, agitation/discomfort, other

• Duration of intervention

• Data to be collected at start, 1 hour, 2 hours and 6 hours (all +- 30

minutes) and 12, 24, 48 hours (+- 60 minutes), during ICU admission.

o Need for sedation (yes/no)

* type of sedation (e.g. dexmedetomedine, clonidine, propofol, opioids,

benzodiazepines, other)

* duration of sedation

o Clinical parameters

* heart rate, respiratory rate, blood pressure, SpO2

* arterial blood gas (pH, PaO2, PaCO2, SpO2, bicarbonate, base excess, lactate)

* dyspnea score (Borg score 0-10)

* Glasgow Coma Scale

* RASS

* Secretions (as 0 (absent), 1 (low quantity), 2 (intermediate), 3 (abundant),

or 4 (very abundant) little to normal/abundant)

o Ventilatory support parameters to be collected

* HFNO: flow, FiO2 and temperature

* NIV: PEEP/EPAP, PS/IPAP, FiO2,

o (dys)comfort score on a 10-point VAS scale (0 = comfortable, 10= most

discomfort imaginable).

o HACOR score (calculated from the abovementioned parameters)

• Facial pressure sores (scored daily: yes/no, severity 1-4)

• Nursing effort:

o Number of nursing respiratory support interventions (peat list per

intervention) per 2 hours for the first 6 hours.

• 30 day mortality

• 90 day mortality

• At 90 days: questionnaire on quality of life (EQ5D and SF-36), anxiety and

depression (HADS), PTSD (IES-R) and dyspnea (CCQ and MRC).

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is frequently complicated by a worsening of symptoms, known as acute exacerbations (AECOPD). These exacerbations can result in a life-threatening condition with an impaired gas exchange, resulting in hypercapnia and as a result respiratory acidosis. The current standard of care of respiratory support for these patients is non-invasive ventilation (NIV), which has been shown to reduce morbidity and mortality. However, NIV is often unsuccessful, due to intolerance, agitation or patient-ventilation dyssynchrony. Furthermore, NIV is a resource-intensive therapy. High flow nasal oxygen (HFNO) is a non-invasive respiratory support mode that provides heated and humidified gas through soft nasal prongs. Several studies have shown that HFNO improves gas exchange and reduces work of breathing in non-hypercapnic respiratory failure. Furthermore, HFNO is thought to be better tolerated than NIV and the nursing effort may be lower compared to NIV. We hypothesise that HFNO is non-inferior to NIV for patients with acidotic, hypercapnic AECOPD regarding the need for intubation and mortality, and that it increases patient comfort and reduces nursing effort.

Study objective

To assess the feasibility of a larger study comparing HFNO with NIV as first line treatment in hypercapnic, acidotic AECOPD.

Study design

prospective, randomized, multi-center, unblinded, pilot study

Intervention

HFNO versus NIV as first line treatment at presentation

Study burden and risks

All participating patients will receive standard of care (i.e., admission to the monitored ward or ICU for intensive monitoring and regular blood withdrawals, steroids, bronchodilator inhalation therapy). There will be one extra questionnaire after 3 months, but no extra blood samples or site visits, compared to regular care for the participating patients. We will ask permission of the patient to register date of hospital discharge and outcome after ICU discharge and ask them to fill out questionnaires at 3 months after admission about their quality of life. Previous studies have not shown that HFNO is inferior to NIV with regards to outcomes (intubation rate, mortality), albeit that they were not powered to prove non-inferiority.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Known chronic obstructive pulmonary disease
• Acute hypercapnic exacerbation of this condition, defined as:
o PaCO2>45 mmHg or >6.0 kPa
o pH 7.25-7.34
• Age >40 years

Exclusion criteria

- Metabolic (component of) acidosis, defined as a bicarbonate <20 mmol/L.

- Non-invasive respiratory support (either NIV or HFNO) already started, e.g.

by ambulance or on the ward.
• Asthma
• Immediate need for intubation, based on clinical judgement of the attending physician.
• Impossibility to apply either one of the two interventions
• Patient not expected to give immediate or delayed informed consent (e.g. cognitive impairment, psychological or mental inabilities).
• Established home-NIV or home CPAP, known indication for home-NIV or CPAP (e.g. OSAS or obesitas hypoventilation syndrome).
• Impeding death
• Concurrent (respiratory) diseases that may influence treatment efficacy: acute heart infarction, cardiogenic lung edema, massive pulmonary embolism (intermediate-high risk or more). NB; pulmonary infections (viral and bacterial) are a common cause of exacerbation and are no reason for exclusion.
• Other acute diseases that preclude participation in the trial such as hemodynamic instability (need for vasopressors), reduced consciousness with need for intubation, severe intoxication
• Tracheostomized patients
• Participation in other interventional trials
• Impossibility to admit the patient to the participating ICU or monitored ward (e.g. medium care / high dependency unit, depending on local infrastructure).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2024
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	High Flow Nasal Oxygen
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-12-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84019.100.23