Does High Flow Nasal Cannula (HFNC) facilitate CO2-washout during EBUS under procedural sedation?

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The objective is to investigate if there is a flow-dependent effect of HFNC on ventilation during an EBUS procedure under procedural sedation in patients with COPD gold class 3-4.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51455

Source
ToetsingOnline

Brief title
Does HFNC facilitate CO2-washout during EBUS?

Condition

- Other condition
- Bronchial disorders (excl neoplasms)
- Respiratory tract therapeutic procedures

Synonym
High flow nasal cannula, ventilation

Health condition

Sedatie

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Gefiinancieerd door de onderzoekers

Intervention

Keyword: CO2 washout, Dead space ventilation, EBUS, High Flow Nasal Cannula

Outcome measures

Primary outcome

The CO2-washout will be measured by:

- insp CO2

- exp CO2

- CO2-waveform analysis

Secondary outcome

Secundary outcomes will be:

- a difference in CO2-washout in different levels of the trachea (carina en

left main bronchus).

- a flow-dependency

There will be controlled for capillary CO2.

Study description

Background summary

HFNC is commonly used during sedation to avoid deoxygenation. However, HFNC also reduces dead space, which facilitates ventilation, as Intensive Care-related research points out.
It is unclear if HNFC also facilitates ventilation when the airway is partially obstructed by a bronchoscope. It is required to investigate this, in order to

avoid false expectations of the use of HFNC during an EBUS-procedure.

Study objective

The objective is to investigate if there is a flow-dependent effect of HFNC on ventilation during an EBUS procedure under procedural sedation in patients with COPD gold class 3-4.

Study design

A randomized controlled trial

Intervention

The patients will start with 3L O2/min through a nasal cannula. This will be replaced by HFNC after 10 minutes, which will be set with a flow of 30 or 70 L/min, depending on the randomisation. After 15 minutes, the flow of the HFNC will be set at the other flow (30 of 70 L/min) during 15 minutes.

Study burden and risks

The additional burden for a patient consists of 4 times a capillary bloodsample during sedation. All other measurements take place during the EBUS, with equipment already being used in the patient.
There is no additional risk, since the intervention (HFNC) is already being used in regular Dutch practice.

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

Adult patients scheduled for EBUS with sedation
COPD gold class 3-4

Exclusion criteria

- Neuromusculaire diseases, such as Guillan Barre, MS, ALS
- allergy to propofol or esketamine
- Systolic pulmonary pressure > 60 mmHg
- Pregnancy
- Children (age <18)
- Upper airway obstruction, such as stenosis or tumour

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-10-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Thrive
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-06-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80926.091.22