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Preventing oxygen desaturation during bronchoscopy in patients with COPD comparing two oxygenation methods

Submission date 22/11/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/02/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/12/2024	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Normally, oxygen is administered during bronchoscopy to maintain the oxygen content in the blood during the examination. For years, we have routinely administered oxygen via nasal cannulae. The nasal HighFlow is now a new method of oxygen application and additionally of ventilation support. The flow rates of this a humidified and heated air stream can vary between 2 - 80 l/min. The use of nasal HighFlow is expected to result in a more constant oxygen saturation during lung imaging and also in an accompanying respiratory support and thus reduction of your oxygen consumption during the examination. In the end we would like to find out whether the use of nasal HighFlow can reduce fluctuations in oxygen saturation and an increase in carbon dioxide (pCO2) in the blood. In addition, we are interested in patient comfort and tolerability of this mode of administration.

Who can participate?
Adults with a previous diagnosis of COPD and a clinical indication for a bronchoscopy.

What does the study involve?
Every participant will randomly receive either oxygen via nasal cannula or nasal HighFlow via the associated nasal cannula during the bronchoscopy. During the examination, they will be closely monitored for blood pressure, pulse, oxygen saturation, and your carbon dioxide level. Afterwards the participants answer a short questionnaire in which they are asked to briefly answer how they felt about the examination.

What are the possible benefits and risks of participating?
There is no direct benefit to participating other than helping future patients undergoing bronchoscopies using the most suitable oxygenation method. With every bronchoscopy there are certain risks. Participating in this study will not increase the risks during the bronchoscopy other than a possible dehydration, irritation or bleeding tendency of the nasal mucosa.

Where is the study run from?
University Hospital of Basel (Switzerland)

When is the study starting and how long is it expected to run for?
March 2021 to December 2023

Who is funding the study?
University Hospital of Basel (Switzerland)

Who is the main contact?
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Public

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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
Preventing oxygen desaturation during bronchoscopy using high flow oxygen vs standard management in COPD patients – PROSA 2 Study

Acronym
PROSA 2

Study objectives
The purpose of this study is to evaluate whether oxygen delivery using HFNO during sedation for bronchoscopy will improve oxygenation in patients with COPD compared to conventional oxygen by nasal cannula. We hypothesise that a 25% decrease in the cumulative hypoxemia time during sedation for bronchoscopy could be achieved using HFNO.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/10/2021, Ethics Committee Northwestern and Central Switzerland (Hebelstrasse 53, 4056 Basel, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch), ref: 2021-01718

Study design
Investigator-initiated prospective randomized controlled superiority multicenter study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Bronchoscopy in COPD patients

Interventions
Patients will be randomized to either receive conventional oxygen by nasal cannula (control group) or high flow oxygen during sedation for bronchoscopy (HFNO/Intervention group)

Intervention Type
Procedure/Surgery

Primary outcome measure
Cumulative hypoxemia time, defined as oxygen saturation <90%, during sedation for bronchoscopy measured using pulse oximetry

Secondary outcome measures
Oxygen saturation, and therefore hypoxemia, will be measured with pulse oximetry. The partial pressure of carbon dioxide will be monitored using capnography.
1. Percentage of patients experiencing any hypoxemia, defined as <90%, during bronchoscopy
2. Percentage of patients experiencing hypoxemia > 60 sec, defined as <90%, during bronchoscopy
3. Duration of hypoxemia, defined as <88%, during bronchoscopy
4. Lowest oxygen saturation during bronchoscopy
5. Average oxygen saturation during bronchoscopy
6. Number of episodes of hypoxemia, defined as <90%, during bronchoscopy
7. Maximal transcutaneous carbon dioxide (tcCO2) during bronchoscopy
8. Average tcCO2 during bronchoscopy
9. Maximal increase of tcCO2 from baseline during bronchoscopy
10. Occurrence of complications, including need for intubation, non-invasive ventilation, cardiac arrest
11. Results will be also analysed by type of bronchoscopic procedures
12. Analysis of patient comfort during examination using a questionnaire

Overall study start date
09/03/2021

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Informed Consent as documented signature
3. Clinical indication for bronchoscopy
4. Prior diagnosis of COPD according to the GOLD criteria

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
600

Total final enrolment
605

Key exclusion criteria
1. Patients intubated at screening time
2. Bronchoscopy via tracheostomy tube
3. Patients requiring intubation for procedure
4. Prior enrolment in an intervention study within the last 30 days
5. Inability or contraindications to undergo the investigated intervention (i.e. active nasal bleeding; recent nasal surgery; base of skull defect or fracture)
6. Patients with oxygen saturation below 88% while breathing room air
7. Patient with hypercapnic respiratory failure (pCO_2 > 6.5kPa) or other indications for non-invasive ventilation for bronchoscopy

Date of first enrolment
08/11/2021

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Germany

Switzerland

Study participating centre
University Hospital Basel
Clinic of Pneumology and Respiratory Cell Research
Petersgraben 4
Basel
Switzerland
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Study participating centre
Universitätsklinikum Freiburg, Klinik für Pneumologie
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.unispital-basel.ch/

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsspital Basel

Alternative Name(s)
University Hospital Basel, University Hospital of Basel, The University Hospital Basel, Hôpital Universitaire de Bâle, L'Hôpital universitaire de Bâle, Das Universitätsspital Basel, UHB

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Switzerland

Results and Publications

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

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/ or analysed during the current study are available from the corresponding author on reasonable request. (Daiana.Stolz@usb.ch)

IPD sharing plan summary
Available on request