

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

<b>Submission date</b> 22/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/12/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 (pCO<sub>2</sub>) 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?  
Prof. Daiana Stolz, Daiana.Stolz@usb.ch  
Vivian Suarez Domenech, vivian.suarezdomenech@usb.ch

## Contact information

### Type(s)

Public

### Contact name

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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 (tcCO<sub>2</sub>) during bronchoscopy
8. Average tcCO<sub>2</sub> during bronchoscopy
9. Maximal increase of tcCO<sub>2</sub> 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

4031

**Study participating centre**

**Universitätsklinikum Freiburg, Klinik für Pneumologie**

Killianstraße 5

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Germany  
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## Sponsor information

### Organisation

University Hospital of Basel

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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