

# Bolus administration versus continuous infusion of Propofol sedation in flexible bronchoscopy

<b>Submission date</b> 03/02/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 03/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/10/2014	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Daiana Stolz

**Contact details**  
Clinic of Pneumology and Respiratory Cell Research  
University Hospital Basel  
Petersgraben 4  
Basel  
Switzerland  
4031

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Bolus administration versus continuous infusion of Propofol sedation in flexible bronchoscopy: a randomised non-inferiority trial

**Acronym**

## Propofol Study

### **Study objectives**

Propofol is a sedative-hypnotic with a rapid onset of action coupled with smooth and rapid recovery. Multiple studies using it as a sedative agent for gastrointestinal endoscopic procedures have shown propofol to be safe and effective. More recently propofol-only sedation was shown to be a feasible and safe sedation method for bronchoscopic procedures as well. In the vast majority of studies an intermittent bolus technique was used. Hardly any data exists for the use of propofol using a continuous infusion as the sedation method in bronchoscopy. To show that for sedation in flexible bronchoscopy the use of propofol using a continuous infusion is associated with a incidence of complications within 5% of that of an intermittent bolus technique, or better.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The study protocol has been submitted to the Ethics Committee, Basel, Switzerland

### **Study design**

Prospective randomised non-inferiority single-centre study

### **Primary study design**

Interventional

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

Pulmonary disease diagnosis, need for flexible bronchoscopy

### **Interventions**

Propofol continuous infusion versus bolus for sedation in flexible bronchoscopy

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

1. Number (percentage) of complications (oxygen desaturation less than or equal to 90%)
2. Need for chin-support
3. Need for nasopharyngeal or oropharyngeal airway insertion
4. Need for intubation
5. Hypotension with a systolic blood pressure of less than 90 mmHg
6. Minor or major bleeding
7. Intensive Care Unit [ICU] need post-bronchoscopy
8. Pneumothorax
9. Need to abort bronchoscopy
10. Death

These outcomes are assessed by the study physician during and up to 24 hours after the procedure

### **Key secondary outcome(s)**

1. Total dose of propofol, dose of propofol per kilogram body weight and per minute
2. Duration of the procedure
3. Mean lowest oxygen saturation during the procedure
4. Mean lowest systolic blood pressure during the procedure
5. Hemodynamic parameters other than blood pressure during and after the procedure
6. Cough scores, as assessed by a Visual Analogue Scale (VAS) by patients, nurses and physicians during and 2 hours after the procedure
7. Patient discomfort
8. Median patient overall well-being (comfort) at 1 and 2 hours after the procedure
9. Willingness to undergo a repeated procedure, assessed by a VAS 2 hours after the procedure
10. Fear of undergoing a repeated procedure, assessed by a VAS 2 hours after the procedure
11. Supplemental lidocaine doses, assessed by the nurse team and study physician during the procedure, as judged by the bronchoscopist
12. Medication doses, assessed by the nurse team and study physician during the procedure, as judged by the bronchoscopist

### **Completion date**

30/09/2012

## **Eligibility**

### **Key inclusion criteria**

1. Patients aged 18 or older
2. Patients undergoing flexible bronchoscopy

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Known allergy to propofol
2. Mental disorder preventing appropriate judgment concerning study participation
3. Pregnancy and breast-feeding
4. Intubated patients

**Date of first enrolment**

01/04/2011

**Date of final enrolment**

30/09/2012

## Locations

**Countries of recruitment**

Switzerland

**Study participating centre**

Clinic of Pneumology and Respiratory Cell Research

Basel

Switzerland

4031

## Sponsor information

**Organisation**

University Hospital Basel (Switzerland)

**ROR**

<https://ror.org/04k51q396>

## Funder(s)

**Funder type**

University/education

**Funder Name**

University Hospital Basel (Switzerland) - Clinic of Pneumology and Respiratory Cell Research

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2014		Yes	No