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# Propofol versus midazolam/hydrocodone for sedation in flexible bronchoscopy: Safety and patient comfort - a non-inferiority trial

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| **Submission date**<br>03/01/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>14/02/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>02/11/2009 | **Condition category**<br>Respiratory | |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Michael Tamm

**Contact details**
University Hospital Basel
Clinic of Pulmonary Medicine and Respiratory Cell Research
Petersgraben 4
Basel
Switzerland
4031
+ 41 61 265 5184
dstolz@uhbs.ch

## Additional identifiers

## Study information

**Scientific Title**

**Study objectives**

The use of propofol for sedation in flexible bronchoscopy is associated with a mean low saturation within 2% of that of the combination of midazolam and hydrocodone, or better.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of Basel (Ethikkommission Beider Basel), approved on 29 August 2006 (ref: 19603)

## Study design
Prospective single-blind randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Sedation for flexible bronchoscopy

## Interventions
Patients will be randomly assigned to propofol (intravenous; iv) or the combination of midazolam and hydrocodone (iv) for sedation during flexible bronchoscopy. The doses of propofol and midazolam vary among the patients, depending on the level of sedation obtained. Hydrocodone will be used in the standard dose of 5 mg iv.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Propofol, midazolam and hydrocodone

## Primary outcome(s)
1. Mean lowest oxygen saturation during the procedure
2. Median patient overall well-being (comfort) at 1 hour after the procedure

## Key secondary outcome(s)
1. Duration of the procedure
2. Hemodynamic parameters during and after the procedure
3. Cough scores, as assessed by a visual analogue scale by patients, nurses and physicians 2 hours after the procedure
4. Patient discomfort
5. Willigness to undergo a repeated procedure, assessed by a visual analogue scale 2 hours after the procedure
6. Fear of undergoing a repeated procedure, assessed by a visual analogue scale 2 hours after the procedure

7. Number (percentage) of complications (desaturation >90%, Chin-support, mild bledding, severe bleeding, nasopharyngeal-tube use, intubation, Intensive Care Unit [ICU] need post-bronchoscopy, hypotension, pneumothorax, death) assessed by the study physician during and up to 24 hours after the procedure
8. Supplemental lidocaine doses, assessed by the nurse team and study physician during the procedure, as judged by the bronchosopist
9. Medication doses, assessed by the nurse team and study physician during the procedure, as judged by the bronchoscopist
10. Median patient overall well-being (comfort) at 2 hours after the procedure

### Completion date
31/03/2008

## Eligibility

### Key inclusion criteria
1. Age >18 years
2. Need for flexible bronchoscopy

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Invasive mechanical ventilation
2. Known allergy or intolerance to midazolam, hydrocodone or propofol
3. Inability to provide informed consent

### Date of first enrolment
02/01/2008

### Date of final enrolment
31/03/2008

## Locations

### Countries of recruitment
Switzerland

**Study participating centre**
**University Hospital Basel**
Basel
Switzerland
4031

# Sponsor information

**Organisation**
University Hospital Basel (Switzerland)

**ROR**
https://ror.org/04k51q396

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Clinic of Pulmonary Medicine and Respiratory Cell Research, University Hospital Basel (Switzerland)

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/11/2009 | | Yes | No |