ISRCTN95930113 https://doi.org/10.1186/ISRCTN95930113

# Propofol versus midazolam in medical thoracoscopy

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 17/06/2011 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 31/08/2011 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 11/07/2017 | Respiratory | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Propofol is a drug that is used to slow the activity of the brain and nervous system (sedative). Studies have shown propofol to be safe and effective as a sedative for bronchoscopic procedures, where an instrument (bronchoscope) is inserted into the airways to look at the inside of the airways. The aim of this study is to assess the feasibility and safety of using propofol for conscious sedation in medical thoracoscopy, where a thin, flexible viewing tube (called a thoracoscope) is inserted through a small cut in the chest.

Who can participate?
Patients aged 18 or older undergoing thoracoscopy

What does the study involve?
Participants are randomly allocated to be sedated with either propofol or midazolam.
All participants also receive hydrocodone and pethidine intravenously (delivered into a vein) and supplemental oxygen is offered via a face mask. Diagnostic and treatment procedures are performed as needed. Blood parameters, sedation, duration of thoracoscopy, indication, procedures and complications are noted during the procedure.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
May 2011 to August 2013

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

Who is the main contact?
Prof. Daiana Stolz

# Contact information

### Type(s)
Scientific

### Contact name
Prof Daiana Stolz

### Contact details
University Hospital Basel
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# Additional identifiers

### Protocol serial number
151/11

# Study information

### Scientific Title
Propofol versus midazolam in medical thoracoscopy: a randomised non-inferiority trial

### Study objectives
Propofol is a sedative-hypnotic with a rapid onset of action coupled with smooth and rapid recovery. Studies using it as a sedative agent for bronchoscopic procedures have shown propofol to be safe and effective. Hardly any data exist about the feasibility and safety of propofol for conscious sedation in medical thoracoscopy.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Basel Ethics Committee, Switzerland, 23/06/2011

### Study design
Prospective randomised non-inferiority single-centre trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Thoracoscopy in pleural effusion/pulmonary disease

## Interventions
Patients will be randomly assigned to either propofol or midazolam.

Patients assigned to the propofol group will receive an initial bolus of intravenous propofol, immediately followed by the continuous infusion. In case of inadequate sedation, a bolus of propofol will be given and the infusion rate will be increased. In case of apnoea, hypoxemia or hypotension, the continuous infusion can be reduced or completely stopped at all times. Midazolam will be titrated in order to achieve adequate conscious sedation (onset of ptosis).

All patients will receive hydrocodone and pethidine intravenously. Supplemental oxygen will be offered via a face mask to all patients.

Diagnostic and therapeutic procedures will be performed dependent upon the clinical indication. Haemodynamic parameters, sedation, duration of thoracoscopy, indication, procedures and complications will be noted during the procedure.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Hydrocodone, midazolam, pethidine, propofol

## Primary outcome(s)
Mean lowest oxygen saturation during the procedure

## Key secondary outcome(s))
1. Duration of the procedure
2. Mean lowest breathing rate during the procedure
3. Mean highest carbon dioxide tension during the procedure
4. Mean lowest systolic blood pressure, mean lowest and mean highest heart rate during the procedure
5. Number (percentage) of complications during the procedure assessed by the study physician during the procedure
5.1. Oxygen desaturation less than or equal to 90 %, need for chin-support
5.2. Need for nasopharyngeal or oropharyngeal airway insertion
5.3. Need for intubation
5.4. Hypotension with a systolic blood pressure of < 90 mmHg
5.5. Minor or major bleeding
5.6. Intensive Care Unit [ICU] need post-thoracoscopy
5.7. Need to abort thoracoscopy
5.8. Death
6. Number (percentage) of complications following the procedure assessed by the study physician up to 4 weeks after the procedure
6.1. Uncontrollable pain
6.2. Subcutaneous emphysema
6.3. Fever > 38.5°C
6.4. Drain site infection
6.5. Empyema

6.6. Pleuro-cutaneous fistula
6.7. Need for intubation
6.8. Bleeding
6.9. Intensive Care Unit [ICU] need
6.10. Need for insertion of an additional chest tube
6.11. Need for re-thoracoscopy
6.12. Death
7. Total dose of propofol and midazolam, respectively; dose of propofol and midazolam per kilogram body weight; dose of propofol and midazolam per kilogram body weight and per minute
8. Medication doses of hydrocodone and pethidine (meperidine)
9. Cough scores, as assessed by a visual analogue scale by nurses during procedure
10. Patient discomfort 24 hours after the procedure
11. Willingness to undergo a repeated procedure, assessed by a visual analogue scale 24 hours after the procedure
12. Fear of undergoing a repeated procedure, assessed by a visual analogue scale 24 hours after the procedure

### Completion date
31/08/2013

## Eligibility

### Key inclusion criteria
1. Patients aged 18 or older
2. Patients undergoing thoracoscopy

### 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, midazolam, hydrocodone or pethidine
2. Mental disorder preventing appropriate judgment concerning study participation
3. Pregnancy and breast-feeding
4. Intubated patients

### Date of first enrolment
01/05/2011

**Date of final enrolment**
31/08/2013

# 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**
University Hospital Basel (Switzerland)

# Results and Publications

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

**IPD sharing plan summary**
Not provided at time of registration