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
Clinic of Pneumology and Respiratory Cell Research
Petersgraben 4
Basel
Switzerland
4031

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
Mean lowest oxygen saturation during the procedure

Secondary outcome measures
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

Overall study start date
01/05/2011

Completion date
31/08/2013

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

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)

Sponsor details
Clinic of Pneumology and Respiratory Cell Research
c/o Prof. Dr. Michael Tamm
Petersgraben 4
Basel
Switzerland
4031

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration