

Propofol versus midazolam in medical thoracoscopy

Submission date 17/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/07/2017	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
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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