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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

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 below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
02/01/2008

Completion date
31/03/2008

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

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)

Sponsor details
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Sponsor type
University/education

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2009		Yes	No