

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/11/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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. Willingness 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 bleeding, 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

c/o Prof Michael Tamm

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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