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Bolus administration versus continuous infusion of Propofol sedation in flexible bronchoscopy

Submission date 03/02/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/05/2011	**Overall study status** Completed	
Last Edited 27/10/2014	**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
Bolus administration versus continuous infusion of Propofol sedation in flexible bronchoscopy: a randomised non-inferiority trial

Acronym
Propofol Study

Study objectives
Propofol is a sedative-hypnotic with a rapid onset of action coupled with smooth and rapid recovery. Multiple studies using it as a sedative agent for gastrointestinal endoscopic procedures have shown propofol to be safe and effective. More recently propofol-only sedation was shown to be a feasible and safe sedation method for bronchoscopic procedures as well. In the vast majority of studies an intermittent bolus technique was used. Hardly any data exists for the use of propofol using a continuous infusion as the sedation method in bronchoscopy. To show that for sedation in flexible bronchoscopy the use of propofol using a continuous infusion is associated with a incidence of complications within 5% of that of an intermittent bolus technique, or better.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol has been submitted to the Ethics Committee, Basel, Switzerland

Study design
Prospective randomised non-inferiority single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Pulmonary disease diagnosis, need for flexible bronchoscopy

Interventions
Propofol continous infusion versus bolus for sedation in flexible bronchoscopy

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
1. Number (percentage) of complications (oxygen desaturation less than or equal to 90%
2. Need for chin-support
3. Need for nasopharyngeal or oropharyngeal airway insertion
4. Need for intubation
5. Hypotension with a systolic blood pressure of less than 90 mmHg
6. Minor or major bleeding
7. Intensive Care Unit [ICU] need post-bronchoscopy
8. Pneumothorax
9. Need to abort bronchoscopy
10. Death
These outcomes are assessed by the study physician during and up to 24 hours after the procedure

Secondary outcome measures
1. Total dose of propofol,dose of propofol per kilogram body weight and per minute
2. Duration of the procedure
3. Mean lowest oxygen saturation during the procedure
4. Mean lowest systolic blood pressure during the procedure
5. Hemodynamic parameters other than blood pressure during and after the procedure
6. Cough scores, as assessed by a Visual Analogue Scale (VAS) by patients, nurses and physicians during and 2 hours after the procedure
7. Patient discomfort
8. Median patient overall well-being (comfort) at 1 and 2 hours after the procedure
9. Willingness to undergo a repeated procedure, assessed by a VAS 2 hours after the procedure
10. Fear of undergoing a repeated procedure, assessed by a VAS 2 hours after the procedure
11. Supplemental lidocaine doses, assessed by the nurse team and study physician during the procedure, as judged by the bronchoscopist
12. Medication doses, assessed by the nurse team and study physician during the procedure, as judged by the bronchoscopist

Overall study start date
01/04/2011

Completion date
30/09/2012

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
702

Key exclusion criteria
1. Known allergy to propofol
2. Mental disorder preventing appropriate judgment concerning study participation
3. Pregnancy and breast-feeding
4. Intubated patients

Date of first enrolment
01/04/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Clinic of Pneumology and Respiratory Cell Research
Basel
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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
University/education

Funder Name
University Hospital Basel (Switzerland) - Clinic of Pneumology and Respiratory Cell Research

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	01/02/2014		Yes	No