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Propofol versus Propofol plus Hydrocodone sedation in flexible bronchoscopy

Submission date	Recruitment status	[ ] Prospectively registered
05/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/06/2010	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Daiana Stolz

Contact details
University Hospital Basel
Clinic for Pulmonary Medicine and Respiratory Cell Research
Petersgraben 4
Basel
Switzerland
4031
+41 (0)61 265 5184
stolzd@uhbs.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title
Propofol versus Propofol plus Hydrocodone sedation in flexible bronchoscopy: a prospective, randomised, placebo-controlled, double-blind study

Acronym
PROHYDE Study

Study objectives
The combination of propofol and hydrocodone is superior to propofol alone to suppress cough during flexible bronchoscopy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics commission of Basel (Ethikkomission beider Basel [EKBB]) approved in on the 2nd of February 2009 (ref: 29/09)

Study design
Randomised placebo controlled double blind intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Sedation for flexible bronchoscopy

Interventions
Patients were randomly assigned to either intravenous propofol or the combination of propofol and hydrocodone (4mg).

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Cough score during the procedure as estimated by the physician using a visual-analogue-scale (VAS)

Secondary outcome measures
1. Total dose of propofol
2. Haemodynamic parameters
3. Patients discomfort, assessed 2 hours after procedure
4. Complications during flexible bronchoscopy
5. Patient reported side effects, assessed 24 hours after procedure

Overall study start date
14/02/2009

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Age > 18 years
2. Requirement of flexible bronchoscopy
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Tracheal Intubation
2. Known allergy or intolerance to hydrocodone or propofol
3. Mental retardation
4. Pregnancy

Date of first enrolment
14/02/2009

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel (Switzerland)

Sponsor details
Clinic for Pneumology and Respiratory Cell Research
Petersgraben 4
Basel
Switzerland
4031
+41 (0)61 265 5184
stolzd@uhbs.ch

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel (Switzerland) - Clinic for Pulmonary Medicine 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