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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

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Additional identifiers

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)

Primary study design
Interventional

Study design
Randomised placebo controlled double blind intervention study

Study type(s)
Diagnostic

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration