

Propofol versus Propofol plus Hydrocodone sedation in flexible bronchoscopy

Submission date 05/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/06/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Protocol serial number
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 (Ethikkommission 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

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