ISRCTN56531234 https://doi.org/10.1186/ISRCTN56531234

Effect of two different forms of propofol administration on sedation during bronchoscopy

Submission date
26/11/2020

Recruitment status
No longer recruiting

Registration date
04/12/2020

Overall study status
Completed

Last Edited
04/01/2021

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Bronchoscopy is a standard procedure for the diagnosis and treatment of lung disease. Despite numerous possible complications, it is considered generally safe. Still, the examination can cause discomfort leading to disturbing and potentially harmful reactions. To reduce stress and difficulties and simplify the procedure, flexible bronchoscopy is normally performed under sedation. The increasing use of flexible bronchoscopy for diagnostic and interventional purposes requires further knowledge of feasible sedation. Current guidelines recommend that sedation should be offered to any patient undergoing flexible bronchoscopy and there is a number of studies aiming to identify the best sedation strategy by testing different drugs in varying doses and different methods of application, but there is no standardized sedation protocol. Propofol is widely used as a sedative for flexible bronchoscopy. However, the amount of propofol used and the level of sedation depends on the proceduralist's discretion. In order to provide stable blood levels of propofol and prevent complications, propofol administration by target-controlled infusion (TCI) has been tested. Considering the characteristics of propofol, the TCI algorithm can predict drug concentrations in the brain. The infusion rate of propofol is set according to the patient's age, weight, height and gender and to target the required concentration. The TCI device will then maintain this concentration by automatically changing the infusion rate. The aim of this study is to determine the impact of Target-Controlled Infusion (TCI) of propofol on sedation quality in patients undergoing flexible bronchoscopy in comparison to patients receiving propofol by intermittent boluses.

Who participated
Adult patients scheduled for elective flexible bronchoscopy

What does the study involve?
Participants receive one of the two types of sedation. Bronchoscopy is performed with continuous monitoring of vital signs and electroencephalogram (EEG). In the TCI group propofol sedation is achieved using a perfusor. Based on individual patient data (gender, age, weight and height), the initial infusion rate is set and subsequently increased in small defined steps every 60 seconds according to clinical assessment of sedation depth until the patient loses consciousness (LOC). At this point, the bronchoscopy is started. If necessary, a bolus of propofol (10-30 mg) is given to deepen sedation. To maintain the required level of sedation during the intervention,

the Infusion rate is increased or decreased. In case of adverse effects such as slow breathing or low blood pressure, the infusion rate is reduced or temporarily stopped. The bolus group patients receive boluses of 20 – 50 mg propofol until LOC is achieved. If necessary, additional boluses of 20 – 40 mg are used.

What are the possible benefits and risks of participating in the study?
The possible benefits of this study are improved sedation quality and better examination conditions. There are no additional risks to participants taking part in this study due to the observational design of the study. Both sedation regimens are well established for sedation during bronchoscopy.

Where is the study run from?
Technical University of Munich (Germany)

When is the study starting and how long is it expected to run for?
February 2014 to March 2015

Who is funding the study?
Technical University of Munich (Germany)

Who is the main contact?
Cornelius Husemann
Cornelius.husemann@mri.tum.de

Contact information

Type(s)
Scientific

Contact name
Mr Cornelius Husemann

ORCID ID
https://orcid.org/0000-0001-5648-601X

Contact details
Klinik für Anästhesiologie und Intensivmedizin
Klinikum Rechts der Isar
Technische Universität München
Ismaninger Straße 22
Munich
Germany
81675
+49 (0)17632258586
cornelius.husemann@mri.tum.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Impact of target-controlled infusion (TCI) of propofol on state- and response-entropy and sedation depth during flexible bronchoscopy

Study objectives
The aim of this observational study is to determine the impact of Target-Controlled Infusion of propofol on sedation quality in patients undergoing flexible bronchoscopy in comparison to patients receiving propofol by intermittent boluses. State and Response Entropy are used to monitor the level of sedation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/08/2014, Ethikkommission der Technischen Universität München (Grillparzerstraße 16, 3. Stock, 81675 München, Germany; +49 (0)89 4140 4371; ethikkommission@mri.tum.de), ref: 260/14 S

Study design
Observational prospective single-centre cohort study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
Due to the observational design of the study no specific intervention related to the study is performed.
Patients scheduled for diagnostic or interventional bronchoscopy are non-randomly assigned in an alternate sequence to receive propofol sedation using either intermittent boluses or Target Controlled Infusion (TCI).
In the TCI group propofol sedation is achieved by a perfusor. Based on individual patient data, the target effect-site concentration (Cet) is initially set to 2 µg/ml. Subsequently Cet is increased in steps of 0.5-1.0 µg/ml every 60s until the patient loses consciousness (LOC) defined as MOAA /S Score < 3 (29). At this point, bronchoscopy is initiated, if necessary, a bolus of propofol (10-30 mg) is given via the perfusor to deepen sedation. To maintain the required level of sedation during the intervention, Cet is titrated up/down with increments of 0.5-1.0 µg/ml. The bolus

group patients receive intermittent boluses of 20 – 50mg propofol until LOC is achieved. If necessary, additional boluses of 20 – 40 mg are applied.

Monitoring of three-channel electrocardiography, heart rate, peripheral oxygen saturation, blood pressure (every 2.5 min) and EEG is recorded continuously. As well as vital signs, endpoints include entropy monitoring to evaluate sedation depth, sedation quality and the total amount of propofol.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Level of sedation measured with Response and State Entropy (RE+SE), expressed as mean ± SEM representing the baseline starting points, the induction period until loss of consciousness (LOC), the LOC itself as a timepoint, and the procedure until the end of bronchoscopy
2. Sedation quality measured using a questionnaire to be completed by proceduralists and assisting nurses right after examination. Sedation quality could be rated using a grading system from Grade 1 = “Patient was very calm, excellent working conditions” up to Grade 6 "Patient was uneasy, not good working conditions". Expressed as numbers n and percentage
3. Total amount of propofol, and duration until LOC and duration of the procedure, expressed as mean ± SEM, measured using a timer function within the recording software, starting right before the sedation starts and ending 10 min after bronchoscopy ends

Key secondary outcome(s))
Adverse effects of the sedation protocol, i.e. heart rate >125 bpm and <50 bpm, blood pressure <90 mmHg, <80% and >120% of baseline, SpO_2 <90% and <80% for >10 sec and respiratory rate <8/min, expressed as number (n) and percentage (%), measured using a monitoring device and software recording every vital sign in real-time every second for HR and SpO_2 and every 2.5 min for respiratory rate during the whole procedure

Completion date
31/03/2015

Eligibility

Key inclusion criteria
Patients scheduled for diagnostic or interventional bronchoscopy with an estimated duration >10 min

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
54

Key exclusion criteria
1. Age <18 years
2. Contraindications to propofol
3. Emergency procedures
4. Pregnancy
5. Cystic fibrosis
6. Mandatory ventilation
7. Acute respiratory insufficiency
8. Tachycardia >125 bpm
9. Tachycardic arrhythmias
10. Acute coronary syndrome
11. Severe heart failure
12. Septic shock
13. Severe hepatic impairment
14. Systolic blood pressure <90 mmHg
15. SpO_2 < 90% without supplemental oxygen at presentation and body mass index > 40 kg/m^2

Date of first enrolment
01/06/2014

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
Germany

Study participating centre
Medizinische Klinik und Poliklinik, Klinikum rechts der Isar der Technischen Universität München
Ismaninger Straße 22
Munich
Germany
81675

Sponsor information

Organisation
Rechts der Isar Hospital

ROR
https://ror.org/04jc43x05

Funder(s)

Funder type
University/education

Funder Name
Technische Universität München

Alternative Name(s)
Technical University of Munich, TUM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Cornelius Husemann (cornelius.husemann@mri.tum.de).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			04/01/2021	No	No