Effect of duration of procedural sedation on postprocedural respiration

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21394

Source
NTR

Brief title
TBA

Health condition

Atelectasis, upper respiratory tract infections

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: UMCG department of Anesthesiologie

Intervention

Outcome measures

Primary outcome

Atelectasis after procedural sedartion

Secondary outcome

Signs and symptoms of upper respiratory tract infections

Study description

Background summary

Background Procedural sedation is used to enable patients to tolerate uncomfortable or painful diagnostic or therapeutic, non-surgical procedures. Practitioners use medication for PSA that can cause cardiorespiratory compromise. A well known side effect of sedatives and opioids is depression of the respiratory system. Hypothetically this depression can result in atelectasis formation and/or respiratory problems, especially if the procedure is protracted. No evidence is available concerning the relationship between the duration of procedural sedation and the formation of atelectasis and/or respiratory symptoms. This study investigates this relationship via a non-invasive method using only proprietary procedures for PSA and a short, 5 question telephonical questionnaire.
• Main research question
Is longer duration of procedures under PSA associated with an increased incidence of atelectasis formation and/or respiratory symptoms
• Design (including population, confounders/outcomes)
Prospective non-randomized trial. Population: patients scheduled for a procedure under PSA with the potential to have a procedure duration of more than 2 hours. Exclusion criteria: previous lung surgery, ASA status 4, COPD GOLD class III or IV, SpO2 on room air (pre-procedural) of <97%. Confounders: obesity, airway compromise, need for an FiO2 of more than 50% during the procedure.
• Expected results
null-hypothesis: There is no relationship between the duration of the procedure under PSA and the incidence of atelectasis and/or respiratory symptoms.

Study objective

There is no relationship between the duration of the procedure under PSA and the incidence of atelectasis and/or respiratory symptoms.

Study design

Post-procedural sedation and 7 days post sedation procedure

Contacts

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Eligibility criteria

Inclusion criteria

o Planned for procedure under PSA performed by the department of anesthesiology
o Passed screening for PSA
o Procedure will potentially last longer than 2 hours
o Procedure performed in prone position
o SpO2 on room air pre-procedurally > 96%

Exclusion criteria

o Procedure with prolonged esophageal or bronchial manipulation
o ASA status IV
o COPD Gold 3-4
o previous lung surgery
o use of CPAP for OSAS
o Use of FiO2 > 50% during procedure
o Use of endotracheal intubation during procedure
o Use of Optiflow during procedure
o need for additional bolusses of esketamine during the procedure

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-01-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	24-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8320
Other	METC-UMCG : METC2019/556

Study results