# 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**
Nationaal Trial Register

**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