Effect of duration of procedural sedation on postprocedural respiration

Gepubliceerd: 24-01-2020 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21394

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Atelectasis, upper respiratory tract infections

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: UMCG department of Anesthesiologie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Atelectasis after procedural sedartion

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Post-procedural sedation and 7 days post sedation procedure

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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%

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-01-2020
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	24-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8320

Register	ID
Ander register	METC-UMCG : METC2019/556

Resultaten