What is the effect of deep procedural sedation with HFNOT on tcPCO2, mitoPO2 and mitoVO2

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Primary objectives: - To examine the effects of deep procedural sedation and use of HFNOT on the tcPCO2.- To determine the effects of deep procedural sedation and use of HFNOT on the mitoPO2Secondary Objective: - To determine the effects of deep…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51298

Source
ToetsingOnline

Brief title
Impact of sedation with HFNOT on tcPCO2, mitoPO2 and mitoVO2

Condition

- Other condition

Synonym
monitored anesthetic care, sedation

Health condition

Patienten die diepe sedatie anesthesie ondergaan met HFNOT

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Carbon dioxide, Mitochondria, Oxygen, Sedation anesthesia

Outcome measures

Primary outcome

- To examine the effects of HFNOT during deep procedural sedation on the tcPCO2

- To determine the effects of HFNOT during deep procedural sedation on the

mitoPO2

Secondary outcome

- To examine the effect of deep procedural sedation with HFNOT on the mitoVO2

- To study the relationship between the tcPCO2 and the standard hemodynamic

and respiratory parameters used during deep procedural sedation.

o Non-invasive blood pressure

o Peripheral Oxygen Saturation

o Heart Rate

o Respiratory Rate

- To evaluate the relationship between the mitoPO2 and the standard hemodynamic

and respiratory parameters used during deep procedural sedation.

o Non-invasive blood pressure

o Peripheral Oxygen Saturation

o Heart Rate

o Respiratory Rate

Study description

Background summary

Deep procedural sedation has seen an increased use indication over the last couple of years aided by the introduction of high flow nasal oxygen therapy (HFNOT) during these procedures. However, this level of deep sedation does come with the increased risk of examining whether a patient is adequately ventilated during this procedure.
The definition of deep sedation is: *a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.* As the definition showed there may be an insufficient ventilation during deep sedation. Therefore, HFNOT is used to ensures that the peripheral oxygen saturation is sufficient. However, there are two potential disadvantages. HFNOT can mask the presence of an insufficient respiratory minute volume and an insufficient gas exchange, which can lead to high arterial CO2 (paCO2) levels. Another risk associated with HFNOT is the fact that high oxygen levels are toxic, and prolonged exposure to high partial oxygen pressures, can cause oxidative damage to cell membranes, collapse of the alveoli in the lungs, retinal detachment, and seizures. Most of this damage can be explained by hyperoxia that increases the 'leak' of electrons from the mitochondrial electron transport chain and the resulting increased generation of reactive oxygen species (ROS). Low paCO2 levels and hyperoxia cannot be examined using standard monitoring techniques therefore, this study will use the transcutaneous carbon dioxide (tcPCO2) a proven technique which correlates well to the arterial CO2 (paCO2) to evaluate whether there is an adequate level of ventilation during deep procedural anesthesia with HFNOT. Moreover, the cutaneous mitochondrial oxygenation (mitoPO2) will be monitored to determine the effects that deep procedural sedation with HFNOT has on the cellular oxygenation.

Study objective

Primary objectives:
- To examine the effects of deep procedural sedation and use of HFNOT on the tcPCO2.
- To determine the effects of deep procedural sedation and use of HFNOT on the mitoPO2

Secondary Objective:
- To determine the effects of deep procedural sedation and use of HFNOT on the

mitoVO2

Study design

Single center observational trial in patients undergoing deep procedural sedation.

Study burden and risks

The transcutaneous carbon dioxide measurements performed by the SenTec Digital Monitoring System (SDMS) and the intracellular oxygen measurements performed by the Cellular Oxygen METabolism (COMET) device are non-invasive and do not require deviation from standard protocol. Mild possible discomfort may arise from the use of the aminolevulinic acid plaster or the COMET Sensor Holder which will be attached to the arm during the study period. Overall the risks are considered negligible and the burden low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age over 18 years
- Acceptable proficiency of the Dutch language
- Scheduled for a procedure requiring deep procedural sedation anesthesia with HFNOT.

Exclusion criteria

- Porphyria
- Known intolerance to components of the ALA plaster
- Presence of mitochondrial disease
- Pregnancy/lactation
- Patients with skin lesions on the measurement location which impede measurements
- Incapability to provide inform consent, due to a mental condition interfering with the ability to understand the provided information

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2023
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL81086.078.22