

Can inertial sensors be used to detect upper airway obstruction?

Published: 01-07-2008

Last updated: 07-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON31847

Source

ToetsingOnline

Brief title

Inertial sensors and airway obstruction

Condition

- Upper respiratory tract disorders (excl infections)

Synonym

airway obstruction, choking

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: inertial sensors, obstruction, upper airway

Outcome measures

Primary outcome

The measurements of the inertial sensors will be related to the measured tidal volumes and airway pressures, as obtained at the various levels of airway obstruction.

Secondary outcome

The measurements of respiratory induction plethysmography as well as clinical signs of airway obstruction will be recorded, as obtained at the various levels of airway obstruction.

Study description

Background summary

The function of the human upper airway is to guarantee unobstructed passage of air to and from the lungs. This can only be accomplished by a complex interaction of anatomical factors, muscles and neurological functions. Perioperatively this interaction is negatively influenced by agents used for general anesthesia and/or sedation, as well as by agents used for postoperative analgesia. Therefore, it is not surprising that this can result in airway obstruction. After several minutes, airway obstruction will lead to hypoxemia, which ultimately will increase morbidity and mortality. It would be ideal if airway obstruction could be directly monitored instead of the effects resulting from the obstruction.

At present, sensors to detect upper airway obstruction are far from ideal, so there is a great need for more reliable airway obstruction sensors. Inertial sensors might be helpful in detecting upper airway obstruction.

Study objective

Can inertial sensors be used to detect upper airway obstruction?

Study design

Preoperatively, inertial sensors as well as routine perioperative monitors

will be applied.

During spontaneous ventilation under general anesthesia, several levels of airway obstruction will be induced for very short periods of time (30 seconds). The period of measurements will take 10 minutes in total.

Intervention

During spontaneous ventilation under general anesthesia, several levels of airway obstruction will be induced for very short periods of time (30 seconds).

Study burden and risks

As the airway obstruction will be induced during general anesthesia, patients will be unaware of the obstruction. We consider the risks of this study to be minimal. Obviously, the sensors which are specific for this study, will comply to all electrical safety requirements applicable to the operation room environment.

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

ASA (American Society of Anesthesiology) class 1-3 patients, age > 18 years, without signs of symptoms of upper airway obstruction or respiratory problems, scheduled for a surgical procedure under general anesthesia.

Exclusion criteria

Ischemic heart disease, allergy for the anesthetics used in this study (propofol/remifentanyl).

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-04-2008

Enrollment: 30

Type: Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22001.018.08