Safety and Effectiveness using DEXmedetomidine sedation versus Propofol/Alfentanil sedation during oesophagus interventions. (SEDEX)

Published: 05-09-2011
Last updated: 29-04-2024

The aim of this study is to determine the patients* and endoscopists experiences and patients* safety with different sedation protocols.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON35831

Source
ToetsingOnline

Brief title
Safety and Effectiveness during DEXmedetomidine sedation.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
gullet cancer, oesophagus cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dexmedetomidine, Effectiveness, oesophagus interventions, safety

Outcome measures

Primary outcome

Main study parameters, reflecting the safety aspect, are measurement of oxygen saturation (SO2) measured by pulse oximetry, exhaled CO2 (capnography), heart rate, arrhythmias (ECG) and blood pressure (non-invasive blood pressure measurement, NIBP) and non-invasive cardiac output monitoring (Nexfin). These hemodynamic parameters are surrogate parameters of pulmonary and cardiovascular problems, experienced by the patient during sedation.

Further study parameters measure the effectiveness of the reached sedation level. These parameters are collected by means of questionnaires before and after the procedure and on the following day. We will also measure sweat conductance as a indicator for patients stress level during the procedure.

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Secondary outcome

not applicable

Study description

Background summary

Barrett*s oesophagus develops as a consequence of chronic gastro-oesophageal reflux disease. It is characterized by abnormal changes in the oesophageal lining that may, in some patients, become dysplastic and lead to oesophageal cancer. Oesophagectomy is the standard treatment for high-grade dysplastic Barrett*s oesophagus or intramucosal cancer; however, it is associated with significant mortality and morbidity. Consequently less invasive surgical techniques, such as endoscopic mucosal resection (EMR) and ablative treatments have been developed and are being used as alternatives for patients who are unsuitable for surgery or who express a preference for less invasive options. However these procedures are long lasting, uncomfortable and stressful for most patients. Furthermore they require patients who are sedated, but easily arousable to provide excellent view to the oesophagus. Conscious sedation is a strategy for improving patient comfort during these procedures. In particular, benzodiazepines and propofol are known to provide excellent sedation. However, this method is often associated with respiratory depression. 50% of the morbidity and 60% of the mortality in upper GI endoscopy are related to sedation-induced hypoxemia. Therefore, other pharmacological agents that induce an adequate level of sedation without respiratory depression are of increasing interest to clinicians. Dexmedetomidine, a selective alpha2 adrenoceptor agonist, as a single agent produces sedation, pain relief, anxiety reduction, stable respiratory rates, and predictable cardiovascular responses. This profile has recently gained increased popularity for procedural sedation.

Study objective

The aim of this study is to determine the patients* and endoscopists experiences and patients* safety with different sedation protocols.

Study design

Study will be performed as a randomized controlled trial.

Intervention

not applicable

Study burden and risks

Measurements were taken during endoscopy and reflect common clinical practice. Patients and gastroenterologists have to fill in questionnaires before and after the intervention.

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 range * 18 years
ASA classification I * III
Patients, undergoing elective oesophagus intervention
Written informed consent

Exclusion criteria

Age range < 18 years
ASA classification IV and V
Allergic reaction to planned medication in the patients* medical history
Unregulated hypertension

Hypovolemia or hypotension (SBP <80 or MAP <50)
Sever bradycardia (rate < 50) and / or related bradydysrhymias (e.g. advanced heart block)
Impaired ventricular functions (EF <30%)
GFR less than 15ml/min or undergoing hemodialysis
End stage liver disease
Substance abuse

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2012
Enrollment:	64
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dexdor
Generic name:	Dexmedetomidine
Product type:	Medicine
Brand name:	Propofol
Generic name:	Propofol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Rapifen
Generic name:	Alfentanil

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-09-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2012
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
EudraCT	EUCTR2011-004206-19-NL
CCMO	NL36861.018.11