Sedation with propofol TCI during ERCP: Is the combination with esketamine more effective and safer than with alfentanil (SPEKA): A randomized controlled multicentre trial

Published: 02-09-2015
Last updated: 19-03-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON45146

Source
ToetsingOnline

Brief title
SPEKA

Condition

- Hepatic and hepatobiliary disorders

Synonym
disorders of the gallblader and bile ducts, Hepatobiliary disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ERCP, esketamine, sedation

Outcome measures

Primary outcome

Main study parameters are the total dosage of propofol, recovery time, and satisfaction with the procedure of patients and endoscopists.

Secondary outcome

Secondary study parameters concerning the safety aspect, are recording of oxygen saturation (SpO2) measured by pulse oximetry, respiratory rate (RR), exhaled CO2 (capnography), heart rate (HR), arrhythmias (ECG) and non-invasive blood pressure (NIBP). These vital parameters will indicate pulmonary and cardiovascular incidents, experienced by the patient during sedation.

Study description

Background summary

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex, often painful gastrointestinal procedure. Since any movement of the patient could considerably affect success of the ERCP, procedures are usually performed under deep sedation. ERCP is often combined with endoscopic ultrasound (EUS) in order to obtain images and information about the digestive tract and the surrounding tissue and organs. Over the last decade the combination of propofol and an opioid has become the standard sedative regime during ERCP in many countries, despite known side effects, such as hypotension and respiratory depression, leading eventually to severe hypoxemia. Opioids, especially when used in combination with sedative-hypnotics, can not only aggravate clinically significant respiratory depression but also increase the incidence of

postoperative nausea and vomiting.
Esketamine, the s-enantiomer of ketamine - is not only a well-known sedative, but also has strong analgesic properties. Furthermore, its sympathomimetic qualities can counteract the hemodynamic depression of propofol, reducing the risk of cardiovascular or respiratory depression during sedation. Esketamine could thus be a safer additive to propofol than opioids to achieve an adequate level of sedation and analgesia with less negative cardiopulmonary side effects due to reduction of the required dosage of propofol and omission of opioids.

Study objective

The aim of this study is to demonstrate that procedural sedation with propofol and esketamine is more effective and will result in less cardiopulmonary depression than sedation with propofol and the opioid alfentanil. Less side effects should also lead to higher safety profiles of this sedation regime.

The primary objective of this study is to determine the effectiveness of propofol/esketamine compared to propofol/alfentanil sedation, both administered by anaesthetic nurses trained in procedural sedation and analgesia (PSA). Considering effectiveness there are four aspects to determine the effectiveness of the propofol/esketamine regime. First, will the synergistic combination of propofol and esketamine result in a dosage reduction of propofol? Secondly, are the levels of sedation and analgesia (without opioids) sufficient to perform the procedure? Thirdly, are patients more satisfied by the combination propofol/esketamine concerning side effects? Fourth, is recovery time shorter? Secondary objectives concern patient safety. Safety is thereby a synonym for a reduction in pulmonary and cardiovascular incidents and complications (hypotension, respiratory depression, hypoxemia) that could be attributed to the respective sedation regime.

Study design

The study will be performed as a randomized controlled multicentre trial.

Intervention

Patients will be randomized to an esketamine and propofol regime (interventional arm) or to an alfentanil/propofol regime (control arm) and studied during the endoscopic procedure.

Study burden and risks

Esketamin is a registered drug, used for analgesia and sedation purposes. Many of the sedationists have experience with this drug due to its common place in general anaesthesia. Potential side effects of esketamin are psychotomimetic

effects such as vertigo or visual disturbances. Potential benefits of esketamin are the reduction of cardiopulmonary incidents due to its symphaticomimetic effects and maintenance of airway reflexes as well as breathing properties, making it a potentially safer sedative agent in combination with propofol than alfentanil. Vital signs will be recorded during ERCP, which is already standard clinical practice. There will be no significant additional burden compared to standard clinical practice.
Patients and gastroenterologist will be asked to fill in questionnaires before and after the intervention; this can be considered as a minimal burden for the patients.

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

The patients must comply with the following criteria in order to be eligible to participate in this clinical study:;Age range * 18 years
ASA classification I * III
Planned ERCP/EUS procedure
Written informed consent

Exclusion criteria

Patient will be excluded if the following criteria are applicable:
Age range< 18 years
ASA classification IV and V
Allergic reaction to planned medication in the patients* medical history
Unregulated hypertension
History of malignant hypertension
Significant ischaemic heart disease
Mentally disordered
History of psychological problems or psychiatric disease
Use of drugs that affect the central nervous system
Substance abuse
Chronic pain
Pregnancy
Seizure disorders
Increased intracranial pressure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-12-2015
Enrollment:	166
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ketanest S
Generic name:	esketamine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Propofol 1% MCT Fresenius
Generic name:	Propofol 1% MCT Fresenius
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Rapifen
Generic name:	Alfentanil
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	02-09-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-09-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2015
Application type:	Amendment

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

ID: 22136
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2015-002667-42-NL
CCMO	NL53999.018.15
OMON	NL-OMON22136