Comparison of different forms of sedation during endoscopie of the bile ducts

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22136

Source
Nationaal Trial Register

Brief title
SPEKA

Health condition

sedation, esketamine, ERCP

Sponsors and support

Primary sponsor: Department of Anesthesiology and , Department of Gastroenterology & Hepatology, Academic Medical Centre,
Source(s) of monetary or material Support: Department of Anesthesiology and , Department of Gastroenterology & Hepatology, Academic Medical Centre,

Intervention

Outcome measures

Primary outcome

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 outcome

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 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.

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.

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.

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

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 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.

Study design

T1: Start of induction of sedation

T2: End of induction (MOAA/S < 2)

SpO2, RR, HR, NIBD, exCO2, arrhythmia

Significant events

MOAA/S 4

T3: Start of procedure (induction scope)

SpO2, RR, HR, NIBD, exCO2, arrhythmia

Significant events

MOAA/S 4

T4:End of procedure (removing scope)

Questionnaire endoscopist: satisfaction, MOAA/S, estimation pain and ease of procedure

T5:Recovery from sedation (MOAAS >4) (ready for transport to recovery room)

SpO2, RR, HR, NIBD, arrhythmia

MOAA/S

Total doses of medications administered

T 6,7,8,9,10,11

Arrival recovery room ,15 min ,30 min, 60 min recovery,
Discharge

SpO2, RR, HR, NIBD, arrhythmia

Aldrete

Patient questionnaire part 2:

VAS score concerning pain, drowsiness, nausea, perception, and mood state

Follow up telephone call on the following day

Questionnaire patient part 3

VAS score concerning pain, drowsiness, nausea, perception, mood state, total satisfaction, physical activity

Intervention

Patient will be randomized to two groups and will receive either an interventional propofol/esketamin sedation regime or a control propofol/alfentanil sedation regime.

Contacts

Public
Department of Anesthesiology - AMC - Meibergdreef 9

S. Eberl
Postbus 22660 H1Z-148

Amsterdam 1100 DD
The Netherlands
Phone: +31 20 5668180, +31 20 5662533 (Secr.)
Scientific
Department of Anesthesiology - AMC - Meibergdreef 9

S. Eberl
Postbus 22660 H1Z-148

Amsterdam 1100 DD
The Netherlands
Phone: +31 20 5668180, +31 20 5662533 (Secr.)

Eligibility criteria

Inclusion criteria

The patients must comply with the following criteria in order to be eligible to participate in this clinical study:

Age range ¡Ý 18 years

ASA classification I ¨C III

Planned ERCP procedure

Written informed consent

Exclusion criteria

Patient will be excluded if the following criteria in the patients¡¡Â medical history are applicable:

Age range < 18 years

ASA classification IV and V

Allergic reaction to planned medication

History of unregulated or malignant hypertension

Significant ischaemic heart disease

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2015
Enrollment:	166
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 17-11-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45146
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5385
NTR-old	NTR5486
CCMO	NL53999.018.15
OMON	NL-OMON45146

Study results