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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22136

Bron
Nationaal Trial Register

Verkorte titel
SPEKA

Aandoening

sedation, esketamine, ERCP

Ondersteuning

Primaire sponsor: Department of Anesthesiology and , Department of Gastroenterology & Hepatology, Academic Medical Centre,
Overige ondersteuning: Department of Anesthesiology and , Department of Gastroenterology & Hepatology, Academic Medical Centre,

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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?

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2015

Aantal proefpersonen:	166
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-11-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45146
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten