Procedural Propofol Sedation with ketamine versus alfentanil and remifentanil.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29416

Source
Nationaal Trial Register

Brief title
KAUP-study

Health condition

We evaluate the role of injection of ketamine as an analgesic component of anesthesia in comparison with the other analgesics (opioids) in procedural sedation and analgesia therapy (PSA) because of the increasing importance of physician’s satisfaction during performing procedures and patient’s comfort.

Sponsors and support

Primary sponsor: Catharina Hospital Eindhoven
Michelangelolaan 2
5623 EJ Eindhoven
The Netherlands
040-2399111
www.cze.nl
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary endpoint of this study is physician’s satisfaction with the applied sedation technique, measured on a Likert five-item scoring system.

Secondary outcome

Observer’s Assessment of Alertness/ Sedation score, Ramsay score, hemodynamic parameters (mean heart rate, mean systolic blood pressure, mean diastolic blood pressure), respiratory parameters (mean Spo2 values, mean end-tidal co2 values, mean respiratory rated and number of apneas during the procedure), times (time of induction, time required for the procedure, sedation time and recovery time), total dosage of medication needed during the procedure, pain, Aldrete score, patients’ satisfaction and side effects (nausea, vomiting).

Study description

Study objective

We hypothesize that propofol combined with ketamine has a optimal physician’s satisfaction, patient’s satisfaction and hemodynamic stability, in comparison with propofol combined with either alfentanil or remifentanil.

Study design

T = 0: before induction

T = 1: start of PSA

T = 2: end of induction PSA

T = 3: start of procedure by physician

T = 4: sedation parameters (every 15 minutes)

T = 5: end of procedure

T = 6: end of PSA

T = 7: start recovery

T = 8: end of recovery / discharge to the ward

Intervention

For sedation, a propofol perfusor will be started combined with ketamine, even administered by perfusor. During the procedure, doses of propofol and ketamine will be fitted to the clinical situation, to reach and maintain an OAA/S score of at least 3 and to consider cardio-respiratory stability. After finishing the procedure by the physician, administration of perfusor medication will be ended.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria are requirement for PSA, patients aged 18 years or older and with an American Society of Anesthesiology class 1 to 3. Patients will be included in this study after given written informed consent before the treatment starts.

Exclusion criteria

Patients will be excluded form the study if they are unable to give informed consent, are pregnant, has a known allergy to either study medication, are receiving treatment for neuromuscular or psychiatric disease or has a physical or communicational disorder.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-06-2014
Application type:	First submission

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
NTR-new	NL4515
NTR-old	NTR4633
Other	:

Study results