Procedural propofol sedation with ketamine versus alfentanil and remifentanil in patients for cardiac ablation.

No registrations found.

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

Summary

ID

NL-OMON20044

Source
Nationaal Trial Register

Brief title
PARK

Health condition

We evaluate the role of administering ketamine as an analgesic component of anesthesia in procedural sedation and analgesia therapy (PSA), compared with other analgesics (opioids), because of the increasing importance of cardio-respiratory stability, patient’s and physician’s satisfaction and comfort during procedures with PSA.

Sponsors and support

Primary sponsor: Catharina Hopsital Eindhoven
Source(s) of monetary or material Support: Catharina Hopsital Eindhoven

Intervention

Outcome measures

Primary outcome

The primary goal of this study is respiratory stability with the applied sedational technique. Differences of at least 10% in respiration rate, number of apneas and oxygen saturation with the applied inspiratory fraction of oxygen, in combination with the administered doses of procedural sedation medication, between three study groups will be compared and is regarded as a statistically significant difference.

Secondary outcome

Secondary outcome measures include:

Observer's Assessment of Alertness/ Sedation score; OAA/S (0 = fully sedated, 5 = not sedated)

Ramsay score; RS (1 = anxious or restless or both, 8 = no response, even to pain)

Hemodynamic parameters (mean heart rate, mean systolic blood pressure and mean diastolic blood pressure)

Times (time required for the induction of PSA, time required for the procedure, total time PSA is administered and total recovery time)

Total dosages of medication administered during the procedure
Numeric Rating Scale; NRS (0 = no pain, 10 = worst imaginable pain)

Aldrete score

Patient's satisfaction (Likert five-item scoring system, 1 = not at all satisfied, 5 = extremely satisfied)

Physician's satisfaction (Likert five-item scoring system, 1 = not at all satisfied, 5 = extremely satisfied)

Side effects (nausea, vomiting)

Other study parameters:

Demographic characteristics (sex, age, length, weight, BMI, ASA physical status)

Medical history (cardiac status, pulmonary status, renal status, diabetes mellitus, other diseases)

Physical history (smoking, alcohol abuses, drugs abuses, history of PONV)

Study description

Background summary

X

Study objective

In this randomized, single blinded controlled trial, we evaluate the role of ketamine as an analgesic component of procedural sedation. We compare the effects of propofol-ketamine versus propofol-alfentanil and propofol-remifentanil for achieving a more acceptable respiratory stability during procedural sedation in patients scheduled for cardiac ablation treatment. We hypothesize that propofol combined with ketamine has an optimal respiratory stability with a significant decrease in respiratory side effects and complications, in comparison with propofol combined with either alfentanil or remifentanil.

Study design

T = 0 Before induction

− Hemodynamic parameters

− Demographic parameters

− Medical and physical history

− Time

T = 1 Start of induction of PSA

− Time

T = 2 End of induction (OAA/S ≤ 3)

− Hemodynamic parameters

− Respiratory parameters

− Sedation score

− Total doses of medications administered

− Time

T = 3 Start of the procedure

− Time

T = 4 (4.1 – 4.9) Repeated every 15 minutes during the procedure

− Hemodynamic parameters

− Respiratory parameters

− Sedation score

− Total doses of medications administered

− Time

T = 5 End of the procedure

− Time

T = 6 End of PSA

− Hemodynamic parameters

− Respiratory parameters

− Sedation score

− Total doses of medications administered

− Aldrete score

− Pain score

− Time

T = 7 During recovery (every 15 minutes) until Aldrete score > 8

− Hemodynamic parameters

− Respiratory parameters

− Sedation score

− Total doses of medications administered

− Aldrete score

− Pain score

− Time

T = 8 After discharge of the patient / procedure

− Patient’s satisfaction

− Physician’s satisfaction

Intervention

For analgesia during procedural sedation, randomly ketamine will be used. An induction dose of 0,1 mg/kg will be administered and ketamine will continuously be administered with a perfusor in a dose of 0,1 mg/kg/h. During the procedure, doses of ketamine will be fitted to the clinical situation, to reach and maintain an OAA/S score of at least 3, to consider hemodynamic stability and to achieve a pain score (NRS) of at least 4. Administration of ketamine will be raised or lowered when actual hemodynamic measurements differ at least 25% from baseline measurements, or if an OAA/S score unlike 3 or a pain score unlike 4 is achieved. Changes in ketamine dosing is showed in the following flowchart. Ketamine will be dosed in a range of 0,05 – 0,4 mg/kg/h. After finishing the procedure by the physician, administration of perfusor medication will be stopped and the recovery period starts, until an Aldrete score of at least 8 is achieved.

Contacts

Public
Catharina Hospital Eindhoven

P.G.T.M. Broeren
Michelangelolaan 2

Eindhoven 5623 EJ
The Netherlands
+31 40 239 9111
Scientific
Catharina Hospital Eindhoven

P.G.T.M. Broeren
Michelangelolaan 2

Eindhoven 5623 EJ

The Netherlands
+31 40 239 9111

Eligibility criteria

Inclusion criteria

Patients were eligible if scheduled for treatment of atrial fibrillation with cardiac ablation under procedural sedation, aged 18 years or older and with an American Society of Anesthesiology (ASA) 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 from the study if they are unable to give informed consent, are pregnant, have a known allergy to either study medication, are receiving treatment for neuromuscular or psychiatric disease or have 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):	01-05-2015
Enrollment:	235
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-03-2015
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	NL4892
NTR-old	NTR5139
Other	MEC-U : PARK-studie

Study results

Summary results

X