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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28894

Source
NTR

Brief title
PARK-study

Health condition

We designed this study to compare the effects of propofol-ketamine versus propofol-alfentanil and propofol-remifentanil for achieving a more acceptable respiratory stability with a decrease in respiratory side effects during PSA for CA treatment.

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: Catharina Hospital Eindhoven
Michelangelolaan 2
5623 EJ Eindhoven

The Netherlands
040-2399111
www.cze.nl

Intervention

Outcome measures

Primary outcome

The primary endpoint of this study is respiratory stability with the applied sedational technique. Differences in respiration rate, number of apneas and oxygen saturation with the applied inspiratory fraction of oxygen, combined with the administered doses of PSA medication, between the three study groups will be compared.

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)v
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)

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

Study objective

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

T = 1 Start of induction of PSA

T = 2 End of induction (OAA/S ≤ 3)

 Hemodynamic parameters

 Respiratory parameters

 Sedation score

 Total doses of medications administered

T = 3 Start of the procedure

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

T = 6 End of PSA

 Hemodynamic parameters

 Respiratory parameters

 Sedation score

 Total doses of medications administered

 Aldrete score

 Pain score

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

T = 8 After discharge of the patient / procedure

 Patient’s satisfaction

 Physician’s satisfaction

Intervention

For sedation, a propofol perfusor will be started at 2 mg/kg/h, with an induction bolus of 0,5 mg/kg. Contemporaneously with propofol, ketamine will be administered via a perfusor at 0,3 mg/kg/h, with an induction bolus of 0,1 mg/kg. During the procedure, doses of propofol and ketamine will be fitted to the clinical situation, to reach and maintain an Observer’s Assessment of Alertness/ Sedation (OAA/S) score of at least 3, a pain score on a Numeric

Rating Scale (NRS) of at least 4 and to consider hemodynamic stability. Propofol will be dosed in a range of 1 – 4 mg/kg/h and ketamine in a range of 0,05 – 0,4 mg/kg/h.

Contacts

Public
Nurse anesthetist (PSA-specialist)
Catharina Hospital Eindhoven
Michelangelolaan 2
5623 EJ
Loes Braam
Eindhoven
The Netherlands
040-2399111 (sein 114521)
Scientific
Nurse anesthetist (PSA-specialist)
Catharina Hospital Eindhoven
Michelangelolaan 2
5623 EJ
Loes Braam
Eindhoven
The Netherlands
040-2399111 (sein 114521)

Eligibility criteria

Inclusion criteria

Patients were eligible if are: scheduled for treatment of atrial fibrillation with CA under PSA, aged 18 years or older, 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, have a know contra-indication to administer either study medication, are scheduled for a repeated procedure, are receiving treatment for neuromuscular or psychiatric disease and 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):	01-06-2015
Enrollment:	120
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4930
NTR-old	NTR5032
Other	van Loon : FHJ

Study results