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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20044

Bron
Nationaal Trial Register

Verkorte titel
PARK

Aandoening

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.

Ondersteuning

Primaire sponsor: Catharina Hopsital Eindhoven
Overige ondersteuning: Catharina Hopsital Eindhoven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

X

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	235
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4892
NTR-old	NTR5139
Ander register	MEC-U : PARK-studie

Resultaten

Samenvatting resultaten

X