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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28894

Bron
NTR

Verkorte titel
PARK-study

Aandoening

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.

Ondersteuning

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Overige ondersteuning: Catharina Hospital Eindhoven
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

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, 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2015
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4930
NTR-old	NTR5032
Ander register	van Loon : FHJ

Resultaten