Procedural Propofol Sedation with ketamine versus alfentanil and remifentanil.

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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.

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

Samenvatting

ID

NL-OMON29416

Bron
Nationaal Trial Register

Verkorte titel
KAUP-study

Aandoening

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.

Ondersteuning

Primaire sponsor: Catharina Hospital Eindhoven
Michelangelolaan 2
5623 EJ Eindhoven
The Netherlands
040-2399111
www.cze.nl
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-06-2014
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	NL4515

Register	ID
NTR-old	NTR4633
Ander register	:

Resultaten