# Remifentanil use for sedation and pain managment during a painful treatment at the emergency department.

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Remifentanil is a usefull medication for procedural sedation and analgesia (PSA) in the emergency department and the recovery time is shorter compared to the frequently used combination propofol / fentanyl?

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON28296

**Bron**
NTR

**Aandoening**

remifentanil, target controlled infusion, procedural sedation, analgesia, recovery time, emergency department, propofol, fentanyl.
procedurele sedatie, pijnstilling, hersteltijd, spoedeisende hulp.

### Ondersteuning

**Primaire sponsor:** Albert Schweitzer hospital, Dordrecht, The Netherlands
M.A.A. van Hooft
**Overige ondersteuning:** Albert Schweitzer hospital, Dordrecht, the Netherlands

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The recovery time ( time between last dose PSA medication and full recovery of the patient).

# Toelichting onderzoek

### Achtergrond van het onderzoek

We would like to know if remifentanil is a useful medication for PSA in the often busy emergency department (ED) and if the recovery time and time till discharge from the ED is shorter compared with the often used combination of fentanyl and propofol.
Prospective randomized not blinded clinical study design. The patient is assigned to one of the three groups:

1 Fentanyl / propofol group

2 Remifentanil-TCI * / propofol group

3 Remifentanil-TCI group *

* Target Controlled Infusion

Outcomes

Primary outcome: recovery time

Secondary outcome: adverse effects/ complications, successful intervention, satisfaction of the specialist about
performing the intervention, adequate analgesia during procedure, satisfaction patient.

Hypothesis:

We expect that remifentanil will be useful medication for PSA at the ED with a shorter recovery time and faster discharge of the patient from the ED compared with the frequently used combination propofol / fentanyl.

### Doel van het onderzoek

Remifentanil is a usefull medication for procedural sedation and analgesia (PSA) in the emergency department and the recovery time is shorter compared to the frequently used combination propofol / fentanyl?

### Onderzoeksopzet

From 5 minutes before the procedure, the vital signs are checked every 5 minutes. Immediately after the procedure, the intervention is evaluated with the doctors involved and the patient. Also, the following
information is listed on the registration form:The medication and total dosage of analgesic, sedative, concomitant medications, antidote, other
medications administered , additional O2 need, deepest Ramsay sedation score, occurrence of incidents / complication and various times (time start PSA, time start surgery, surgery end time, date last gift PSA medication, time patient fully recovers from PSA, patient discharge time).

**Onderzoeksproduct en/of interventie**

There are three groups in which different PSA medication is administered.
One group gets fentanyl and propofol which is a often used combination of medication for PSA (this is the active control).First dose fentanyl is 1ug/kg iv. First dose propofol is 0,25 mg/kg iv. The dose is titrated to effect.
One group gets remifentanil with a TCI pump (Target Controlled Infusion (TCI) with an approved infusion pump, which is equipped with the Minto pharmacokinetic model with covariates for age and lean body mass) and propofol. The target plasma concentration remifentanil starts with 1 ng/ml and can be titrated to effect till a maximum target plasma concentration of 5 ng/ml. First dose propofol is 0,25 mg/kg iv. The dose is titrated to effect.
One group will get only remifentanil, with a TCI pump (Target Controlled Infusion (TCI) with an approved infusion pump, which is equipped with the Minto pharmacokinetic model with covariates for age and lean body mass).The target plasma concentration remifentanil starts with 1 ng/ml and can be titrated to effect till a maximum target plasma concentration of 5 ng/ml.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All the patients who need procedural sedation and analgesia at the emergency department or the observatorium of the Albert Schweitzer hospital location Dordwijk in Dordrecht, age 18 years and older, classified as ASA I en II.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Age under 18 years, hemodynamic and/or respiratory instable, classified as ASA III, IV and V, suspicion of elevated intra-cranial pressure, pregnancy, use of opiates at home, opiates administered before PSA procedure started (in the ambulance, on arrival at the emergency department), intoxication, known allergy for fentanyl propofol remifentanil soy or chicken proteins.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |

| | |
|---|---|
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 29-12-2014 |
| Aantal proefpersonen: | 60 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 03-07-2015 |
| 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 | NL5100 |
| NTR-old | NTR5232 |
| Ander register | EudraCT number: 2013-003220-36, METC file number: NL45112.101.14 : ABR Number 45112 |

# Resultaten