Remifentanil use for procedural sedation and analgesia in the emergency department

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Answering the following questions:1. Main question: Is remifentanil a usefull medication for PSA in the emergency department?2. What is the recovery time of the patient when using fentanyl / propofol / remifentanil (time between last gift PSA...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON40569

Source
ToetsingOnline

Brief title
Remifentanil use for PSA in the emergency department

Condition

- Cardiac arrhythmias
- Bone and joint injuries
- Skin and subcutaneous tissue therapeutic procedures

Synonym
discharge from hospital, recovery time

Research involving
Human

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis

Source(s) of monetary or material Support: Albert Schweitzer ziekenhuis te Dordrecht

Intervention

Keyword: analgesia, emergency department, procedural sedation, remifentanil

Outcome measures

Primary outcome

Primary outcome:

- The recovery time (time between last dose PSA medication and full recovery

of the patient).

Secondary outcome

Secondary outcome

- Adverse effects, complications.

- Succesfull interventions.

- Satisfaction of the specialist about performing the intervention.

- Adequate analgesia during procedure.

- Satisfaction patient.

Study description

Background summary

An important task of the emergency physician is adequate pain control. Use can be made of Procedural Sedation and Analgesia (PSA) for short-term very painful procedures. This allows a skilled doctor to give the patiënt a level of sedation that makes implementation of the specific procedure possible without being uncomfortable for the patient. Often,used medication for PSA are fentanyl, propofol (Diprivan).

Remifentanil (Ultiva) is a selective *-opioid agonist with a rapid onset (1-2 minutes) and a very short duration (effective half-life 3 to 10 minutes). It is currently used mainly as an analgesic during induction and / or maintenance of

general anesthesia and as analgesia in mechanically ventilated intensive care patients 18 years and older.

The strong analgesic effect, with a rapid onset and a very short duration suggests that remifentanil is a useful medication for procedural sedation in Emergency Medicine. A short recovery time is better patient care because the duration of posibble side effects is shorter and the patient may be discharged earlier. Also important is that the emergency department is a very busy department, therefore it is important to be efficient with the available space and the use of existing staff. When the recovery time of the patient after PSA is shorter the patient is not only discharged earlier but this also means that the nurse responsible for monitoring and the space used are available sooner for another patient.

Study objective

Answering the following questions:
1. Main question: Is remifentanil a usefull medication for PSA in the emergency department?
2. What is the recovery time of the patient when using fentanyl / propofol / remifentanil (time between last gift PSA medication and full recovery of the patient)?
3. Is there a difference in the occurrence of adverse effects / complications such as desaturation / apnea / drop in blood pressure / nausea / vomiting compared to the use of fentanyl / propofol?
4. Is the length of stay shortened with the use of remifentanil in relation to the use of fentanyl / propofol?
5. Is the specialist satisfied about the treatment given during the procedure?
6. How much is the pain experienced by the patient during the procedure?
7. Is the patient satisfied after the treatment?

Study design

Prospective randomized clinical study design. The study is not blinded. The patient that needs PSA will be classified (after informed consent, present inclusion criteria, without exclusion criteria) after randomization in one of the following groups.

1. Fentanyl / propofol group
2. Remifentanil-TCI * / propofol group
3. Remifentanil-TCI group *
* Target Controlled Infusion

Before starting the procedure, the following information will be noted on the registration form.
General: patient study number, date procedure, name and function sedative

doctor, name and title doctor performing the ttraetment, indication procedure.
Patient data: age, gender, height (cm), weight (kg), relevant history, relevant medications, allergies, ASA classification, time last meal solid food / milk, time last meal clear liquid.
Vital signs: heart rate, noninvasive blood pressure, respiratory rate, saturation

During the procedure
During PSA the heart rate, saturation, respiratory rate and ETCO2 is monitored continuously and the non-invasive blood pressure is measured every 5 minutes. This is noted on the registration form, time 0 (start time) is the time at which th administration of the PSA medication started(fentanyl / propofol / remifentanil) and time 5, 10, 15, 20 etc are the following minutes when the vital parameters are noted on the registration form.

After the procedure, the following information is noted on the registration form.
Medication and total dose: given analgesic, sedative, co-medication, antidote, other medications administered.
Extra O2 requirement: no, nasal cannula 2-4 L, 15 liters non rebreathing mask, laryngeal mask, intubation, otherwise.
Deepest Ramsay sedation score.
Have there been incidents/complications: hospitalization due to PSA, aspiration, agitation, apnea longer than 20 seconds, saturation below 90% for more than 60 seconds, systolic blood pressure less than 90 mmHg, heart rate slower than 50/min, nausea, vomiting, dizziness , other.
Performed intervention: stimulation, extra O2, airway maneuvers, ventilation, intubation, medication
Times: PSA start time, start time intervention, end time intervention, time last gift PSA medication (fentanyl / propofol / remifentanil by TCI), time patient fully recovers from PSA, patient discharge time.

After the procedure, the patient is still observed and vital signs: heart rate, noninvasive blood pressure, respiratory rate and saturation are noted on the registration form. Patient may be discharged when there is an adequate level of consciousness, vital signs are stable, patient is able to drink and is not nauseous.
The following details are noted on the registration form.
Is the original interventione successfull.
How was the original intervention performed: easy, normal or hard.
Is the doctor who performed the original intervention satisfied with the sedation and analgesia.
Is the patient satisfied, 0-10 scale (0 not satisfied at all and 10 completely satisfied).
What is the pain score during PSA, 0-10 scale (0 = no pain, 5 = moderate pain and 10 is worst pain imaginable).
Is there amnesia.

Time when patient is fully recovered, time of discharged

Intervention

There are three groups in which different PSA medication is administered

One group gets fentanyl and propofol
One group gets remifentanil 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.
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).

Study burden and risks

PSA is a common treatment given in the emergency department. The use of remifentanil with TCI pump gives no risks other than the currently used medication when PSA is given such as fentanyl and propofol. We expect no increased risk of complications in the study population. Since the duration of the study is limited to the emergency room visit of the patient, the burden for the patient are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-12-2014
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	diprivan
Generic name:	propofol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	fentanyl
Generic name:	fentanyl
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	remifentanil
Generic name:	ultiva
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	15-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-05-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-02-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	01-07-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2013-003220-36-NL
CCMO	NL45112.101.14