Recall of cardioversion after procedural sedation with propofol

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23740

Source
NTR

Brief title
Recall

Health condition

Patiënts with persistent arrhythmias for which cardioversion is indicated

Sponsors and support

Primary sponsor: MCH Westeinde
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The incidence of a recall in patients who underwent cardioversion and were sedated with propofol

Secondary outcome

The difference in NRS score (recall) directly after and some days after cardioversion

Study description

Background summary

The original pilot study is extended to a prospective multicenter study. In this study 223 patients were included. The primary outcome did not differ. The primary outcome was the incidence of painful recall of the ECV after sedation with propofol. Secondary outcomes were pain at the side of the defi-pads and muscle pain after the procedure.

Painful recall in elective electrical cardioversion with propofol and the need for additional analgesia.

Abstract:

Introduction

Electrical cardioversion (ECV) is a short but painful procedure for treating cardiac dysrhythmias. There is a wide geographical variation regarding the medication strategy to facilitate this procedure. Many different anaesthetic techniques for ECV are described. Currently, the optimal medication strategy to prevent pain in ECV had yet to be established. The role for additional analgesic agents to prevent pain during the procedure remains controversial and evidence is limited.

Methods

We conducted a prospective multicenter study to determine the incidence of painful recall in ECV with propofol as a sole agent for sedation, in order to assess the indication for additional opioids. Exclusion criteria were suspected hypersensitivity to propofol. In all patients anaesthesia for ECV was induced with propofol titrated till loss of eyelash reflex and non-responsiveness to stimuli, corresponding to Ramsay Sedation Score level 5-6. ECV was performed with extracardiac biphasic electrical shocks. The primary outcome was painful recall of the procedure, defined as NRS ≥4. Secondary outcome parameters were pain at the side of the defi-pads and muscle pain after ECV.

Results

A total of 226 patients were enrolled in this study. Six patients were excluded due to missing date or violation of study protocol. One patient (0.4%) reported recall of the procedure and NRS 7, despite adequate sedation with 90 mg propofol. Complete amnesia was observed in 223 patients, with NRS 0. The mean of the total dose of propofol was 1.1 mg. Fifteen patients

(6.4%) experienced pain at the side of the defi-pads and six patients (0.9%) complained of muscle pain after the procedure.

Conclusions

In this prospective multicenter study, painful recall of the ECV was found in 0.4% of the patients. Propofol as a sole agent provided effective sedation and amnesia in 98,7 % of the patients. This data supports that additional opioids to propofol sedation is not indicated to prevent pain or recall in ECV.

Study objective

Some patients have painful memories of the cardioversion even though they are sedated with propofol.

Study design

1 Before cardioversion

2 Directly after cardioversion

3 Some days after cardioversion

Intervention

NRS-painscore before, directly after and some days after cardioversion

Contacts

Public
Resident Intensive Care
MC Haaglanden
D.F.M. Winden, van
Den Haag
The Netherlands
-
Scientific
Resident Intensive Care
MC Haaglanden
D.F.M. Winden, van
Den Haag
The Netherlands
-

Eligibility criteria

Inclusion criteria

Patients >18 years old, admitted for scheduled cardioversion of persistent arrhythmia

Exclusion criteria

- An inability to understand the questions (eg, language problems)

- Protein or soy intolerance

- Chronic pain

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2014
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL4646
NTR-old	NTR4789
Other	- : -

Study results