Recall of cardioversion after procedural sedation with propofol

Gepubliceerd: 15-09-2014 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON23740

Bron
NTR

Verkorte titel
Recall

Aandoening

Patiënts with persistent arrhythmias for which cardioversion is indicated

Ondersteuning

Primaire sponsor: MCH Westeinde
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

1 Before cardioversion

2 Directly after cardioversion

3 Some days after cardioversion

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

- Protein or soy intolerance

- Chronic pain

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2014
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL4646
NTR-old	NTR4789
Ander register	- : -

Resultaten