Preventive Methods for Reduction of Pain associated with Propofol Injection: a randomised controlled trial of commonly used methods

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In this randomised controlled trial we compare three commonly used preventive methods to reduce the pain on injection op (PIP) with a control group. Our primary goal is to try and establish the most effective and easy to use method for preventing...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Administration site reactions
Study type	Observational non invasive

Summary

ID

NL-OMON36046

Source
ToetsingOnline

Brief title
Preventive Methods for Reduction of Pain associated with Propofol Injection

Condition

- Administration site reactions

Synonym
Pain Injection

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Stichting Catharina-Ziekenhuis

Intervention

Keyword: Propofol Injection Pain Lidocain

Outcome measures

Primary outcome

Our primary goal is to try and establish the most effective and easy to use

method for preventing PIP, without slowing induction of anaesthesia.

Secondary outcome

Secondary goal is to try and find a correlation between pain on IV-cannulation

and the experience of PIP.

Study description

Background summary

Pain upon injection of the most commonly used narcotic propofol is a frequently occurring problem on induction of anaesthesia. Several preventive methods have been described to reduce the incidence and severity of this pain, but until now no method has been described as best clinical practise yet.

Study objective

In this randomised controlled trial we compare three commonly used preventive methods to reduce the pain on injection op (PIP) with a control group. Our primary goal is to try and establish the most effective and easy to use method for preventing PIP, without slowing induction of anaesthesia. Secondary goal is to try and find a correlation between pain on IV-cannulation and the experience of PIP.

Study design

randomised controlled trial

Study burden and risks

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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

ASA 1 and 2 patients, aged 18-80 years, who will undergo an elective surgical procedure under general anaesthesia

Exclusion criteria

use of NSAIDs or opiates on a regular basis or if communication of psychological disorders are present. Further exclusion criteria are history of polyneuropathy, pre-existing underlying

pathology associated with pain, known hypersensitivity to lidocaine, propofol, lipid emulsions, egg or egg products, emergency surgery, pregnancy and patients using antidepressant medications

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2011
Enrollment:	436
Type:	Actual

Ethics review

Approved WMO

Date:	10-08-2011
Application type:	First submission
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
CCMO	NL36325.060.11