The influence of epidural blockade with ropivacaine on the pharmacokinetics and pharmacodynamics of propofol sedation

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1.To evaluate the influence of epidural blockade with ropivacaine on the pharmacokinetics of propofol.2.To evaluate the influence of epidural blockade with ropivacaine on the pharmacodynamics of propofol. This includes both the sedative and the...

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

Summary

ID

NL-OMON34206

Source
ToetsingOnline

Brief title
Epidural ropivacaine and the pharmacokinetics / -dynamics of propofol

Condition

- Other condition

Synonym
epidural analgesia

Health condition

patienten die een epiduraal nodig hebben voor een operatie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: epidural, pharmacodynamics, pharmacokinetics, propofol

Outcome measures

Primary outcome

To evaluate the influence of epidural blockade with ropivacaine on the

pharmacokinetics of propofol.

To evaluate the influence of epidural blockade with ropivacaine on the

pharmacodynamics of propofol. This includes both the sedative and the

hemodynamic effects.

Secondary outcome

hemodynamic parameters

Study description

Background summary

Recently, various studies report on the hypnotic sparing effect of central neuraxis blockade. Local anaesthetics have been shown to enhance sedation and reduce the hypnotic dose requirements.Up until now, the mechanism and the magnitude of the sedative sparing effect of central neuraxis blockade remain unclear.
The pharmacokinetics of intravenous sedatives may be affected by an epidurally induced change in distribution or clearance of these agents, the pharmacodynamics of intravenous agents may be affected through the deafferentation that occurs when central neuraxis blockade is installed.
We propose to study the influence of epidural blockade with ropivacaine on the pharmacokinetics and pharmacodynamics of propofol when given as intravenous premedication.

Study objective

1.To evaluate the influence of epidural blockade with ropivacaine on the pharmacokinetics of propofol.
2.To evaluate the influence of epidural blockade with ropivacaine on the pharmacodynamics of propofol. This includes both the sedative and the hemodynamic effects.

Study design

randomized, double-blind, placebo-controlled

Intervention

There are 4 groups of 7 patients. The patients in group 1 will receive no ropivacaine (10 ml of epidural NaCl 0.9%), the patients in group 2 will receive 50 mg of epidural ropivacaine 7.5 mg/ml, the patients in group 3 will receive 100 mg of epidural ropivacaine 7.5 mg/ml and the patients in group 4 will receive 150 mg of ropivacaine 7.5 mg/ml.
After the epidural blockade has reached its maximal level. Patients will receive a target controlled infusion with propofol with an initial target concentration of 1 µg/ml. After 6, 12 and 18 min this target propofol concentration will be increased to 2.5 µg/ml, 4 µg/ml and 6 µg/ml. Every 3rd min, the Ramsay sedation score, the eyelash reflex, the BIS score and state of consciousness will be tested and an arterial blood sample will be taken for blood propofol concentration determination. After the loading dose ropivacaine epidurally we will take according to a predetermined blood sampling schedule samples to determine the ropivacaine plasma concentrations.

Study burden and risks

The intravenous line is included in the standard anaesthetic care for scheduled surgical procedures. The arterial will be placed for study purposes. Due to the venous and/or arterial line some bruising may occur. In this study, duration of venous line placement will not prolong the normal stay of lines. The arterial line will be removed directly after termination of the study.

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 class I-II
•Age 18-65 years
•Patients scheduled for surgery requiring epidural anaesthesia and sedation.

Exclusion criteria

•Patients with a BMI >30.
•Participation in a trial on investigational drugs within 3 months prior to the study.
•Known history of hepatic, renal disease or other disease as judged by the investigators.
•Bleeding or coagulation disorders
Patients receiving chronic analgesic therapy.
•Patients using β-blockers
•Pregnancy or lactation.
•Alcohol or drug abuses or history of alcohol/drug abuses.
•Documented or suspected soybean protein and/or drug allergy or amide type local anesthetic allergy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2010
Enrollment:	28
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Propofol
Generic name:	Propofol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ropivacaine
Generic name:	Ropivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	26-07-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	28-07-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2010-020050-34-NL
CCMO	NL32295.058.10