Comparison of the effects of atropine on haemodynamics and tissue oxygenation in anaesthesia with propofol and sufentanil versus propofol and remifentanil.

Published: 05-03-2013
Last updated: 24-04-2024

To investigate if there is a clinically important different effect of atropine on haemodynamic variables, tissue oxygenation or microcirculation during anaesthesia with either sufentanil and propofol or with remifentanil and propofol.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON38529

Source
ToetsingOnline

Brief title
Atropine effects in anaesthesia with Sufentanil vs. Remifentanil.

Condition

- Coronary artery disorders

Synonym
CABG, Open Heart Surgery

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie- onderzoeksbureau
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anaesthesia, atropine, haemodynamic variables, tissue oxygenation

Outcome measures

Primary outcome

The change in CO (continuous measurement of the Nexfin monitor) around the

moment of atropine administration.

Secondary outcome

The evolution of MAP, SctO2 and SptO2 around the moment of atropine

administration.

Study description

Background summary

Induction of general anaesthesia with a combination of opiates and hypnotics often induces vasodilation resulting in several haemodynamic effects such as a decrease in blood pressure, heart rate and cardiac output. This haemodynamic suppression may jeopardize tissue oxygenation, particularly cerebral oxygenation. Previous research of our group (see attachments) has revealed that atropine has an exceptionally beneficial effect on the determinants of tissue oxygen delivery as well as on tissue oxygenation. We have demonstrated a significant and clinically relevant increase in cardiac output (CO) and cerebral tissue oxygenation (SctO2) for a desired increase in arterial blood pressure. This is in steep contrast with the more usual clinical practice of administrating classical vasoactive medication such as phenylephrine or norepinephrine, since the two latter have an even negative effect on CO and SctO2. In our previous research we used standardized target controlled propofol/remifentanil infusions for induction and maintenance of anaesthesia. It is known that remifentanil has more intense haemodynamic side-effects compared to other opiates such as fentanyl, sufentanil or alfentanil. This raises the question whether the beneficial effect of atropine is restricted to

propofol/remifentanil anaesthesia, or if this is equally valid during anaesthesia of propofol combined with other opiates such as sufentanil. Patients undergoing off-pump coronary artery bypass grafting (CABG) require a long and deep general anaesthesia, which is usually performed with the combination of drugs as mentioned above. Because these patients often experience severe haemodynamic fluctuations they need to be closely monitored.

Study objective

To investigate if there is a clinically important different effect of atropine on haemodynamic variables, tissue oxygenation or microcirculation during anaesthesia with either sufentanil and propofol or with remifentanil and propofol.

Study design

Prospective, double-blind, randomized, interventional trial.

Intervention

Patients will be randomised to receive anaesthesia with propofol and an equipotent effect site concentration of either sufentanil or remifentanil administered with target controlled infusion pumps.

Study burden and risks

In this study, we will provide standardized anaesthesia during routine clinical practice. Both sufentanil are remifentanil are routinely used as analgesic, with no definite advantage of either. Whether the patient will be treated with sufentanil or remifentanil will be randomly determined. In these patients an arterial catheter is routinely placed for continuous blood pressure monitoring and blood sampling, consequently no additional punctures are required for the use of the additional monitoring devices. This study will not extent the burden for patients. As both agents are routinely used, patients will have no additional risk or advantage compared to clinical practice.

Contacts

Public
Selecteer

hanzeplein 1
groningen 9713 EZ
NL

Scientific
Selecteer

hanzeplein 1
groningen 9713 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age: 18 years and older
-- Written informed consent to participate in this study.
- Elective CABG surgery performed off-pump.
- Patient and surgical procedure appropriate for treatment with either sufentanil or remifentanil.

Exclusion criteria

- Refusal to participate in this study.
- Age: younger than 18 years.
- Pregnant.
- BMI > 35 kg/m2.
- Patients in which atropine is contra-indicated.
- Patients in which sufentanil or remifentanil at the proposed doses are contra-indicated.
- Urgent or emergency surgery.

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2013
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	sufentanil
Generic name:	sufenatnil
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ultiva
Generic name:	remifentanil
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-05-2013
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTRnl 20130219 -NL
CCMO	NL43791.042.13