Evaluation of the effects of the addition of atropine during propofol/remifentanil induction of anesthesia on hemodynamics, microvascular blood flow and tissue oxygenenation in patients undergoing ophthalmic surgery.

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To determine whether there are clinically important beneficial effects of the addition of atropine during induction of anesthesia with propofol/remifentanil on the hemodynamic profile and on peripheral and cerebral tissue oxygenation and...

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

Summary

ID

NL-OMON37131

Source
ToetsingOnline

Brief title
Atropine-effect during propofol/remifentanil induction

Condition

- Other condition

Synonym
hemodynamice and bloodpressure

Health condition

inductie en de hemodynamiek bij oogoperatie waarbij algehele narcose nodig is

Research involving
Human

Sponsors and support

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

Intervention

Keyword: atropine, hemodynamics, inductie, tissue oxygenation

Outcome measures

Primary outcome

The evolution of heart rate, arterial blood pressure, cardiac output, the

peripheral tissue oxygenation (thenar) and cerebral oxygen saturation

(forehead) and buccal microcirculation.

Secondary outcome

Is the requirement of other vasoactive medication (norepinephrine) for

hemodynamic control different between the two groups?

Study description

Background summary

Remifentanil is a widely used potent intravenous opioid with the advantage of having a short time of action. Compared to other opiates however remifentanil generates more intense hemodynamic side-effects. In ophthalmic surgery the specific anesthesiological challenges necessitate the administration of a combination of relatively high doses of hypnotics and analgesics on the one hand and a short time for postoperative recovery from anesthesia on the other. A primary concern during this deep propofol/remifentanil anesthesia is preserving hemodynamic stability and adequate tissue oxygenation. Previous research of our group has revealed that atropine has an exceptionally beneficial effect on hemodynamics as well as on tissue oxygenation. Our

research (included in the attachments) has demonstrated a clinically very significant 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/or SctO2. In this former research, we administered the atropine only after the onset of clinically important hypotension, as is usual in clinical practice. However, since most patients eventually require some type of pharmacological hemodynamic support, we consider it beneficial to anticipate a decrease in blood pressure to pursue maximal hemodynamic homeostasis. Therefore, we hypothesize that administration of intravenous atropine during induction of propofol/remifentanil may have a positive effect on the hemodynamic profile and peripheral and cerebral tissue oxygenation during and after induction of anesthesia. Establishing the most beneficial therapeutic intervention to reduce the hemodynamic side effects of pharmacological hemodynamic support and improve tissue oxygenation during propofol/remifentanil anesthesia may also improve our understanding of the distinctive effects of remifentanil on the autonomous nervous system as well as the interplay between macro- and microcirculation.

Study objective

To determine whether there are clinically important beneficial effects of the addition of atropine during induction of anesthesia with propofol/remifentanil on the hemodynamic profile and on peripheral and cerebral tissue oxygenation and microvascular blood flow in patients undergoing ophthalmic surgery.

Study design

Prospective double-blind randomized placebo-controlled study

Intervention

All patients will receive a standard anesthesia based on propofol and remifentanil. During the induction of anesthesia patients will randomly receive either atropine (0.5 mg in 1ml) or saline (1 ml). If necessary, hemodynamic support will be provided by continuous infusion of norepinephrine as in normal clinical practice to maintain adequate perfusion pressure defined as mean arterial pressure >= 60 mmHg. Hemodynamic parameters as well as peripheral and cerebral tissue oxygenation and microvascular blood flow will be monitored noninvasively and recorded

Study burden and risks

All patients will receive standardized anesthesia treatment with propofol and remifentanil. In routine clinical practice for this anesthesia and procedure,

depending on the experience of the anesthesiologist, atropine is given preventively at induction of anesthesia or not. The only intervention in this study is that patients will be randomised to be preventively treated with atropine or not. Both preventive administration of atropine or waiting for clinical signs of bradycardia before atropine administration are considered *good clinical practice*. If necessary, additional hemodynamic support will be provided. All additional monitoring devices are noninvasive.
Therefore this study will not extent the burden or risks for patients

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

Patients requiring general anaesthesia.
- Patient*s age >= 18 years and older.

- Patient and surgical procedure appropriate for treatment with either sufentanil or remifentanil.

Exclusion criteria

- Patient*s refusal
- Patient*s age < 18 years
- Patients in which atropine is contra-indicated, such as severe aortic valve stenosis, hypertrophic cardiomyopathy or coronary artery disease
-pregnancy

Study design

Design

Study type:	Interventional
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):	17-09-2012
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	atropine
Generic name:	atropini sulfas
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-09-2012
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	EUCTR2012-002834-36-NL
CCMO	NL41174.042.12