Comparison of the effects of phenylephrine and norepinephrine on hemodynamics and tissue oxygenation in patients undergoing ophthalmic surgery.

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Determine whether phenylephrine or norepinephrine has superior haemodynamical effects in ophtalmic surgery

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

Summary

ID

NL-OMON35495

Source
ToetsingOnline

Brief title
Phenylephrine versus Norepinephrine in ophthalmic surgery.

Condition

- Other condition
- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
hypotension due to anesthesia

Health condition

Geen specifieke aandoening, slechts ter coupering van de hypotensie veroorzakende, routine gebruikte, anesthetica

Research involving
Human

Sponsors and support

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

Intervention

Keyword: general anesthesia, hemodynamics, ophthalmic surgery, tissue oxygenation

Outcome measures

Primary outcome

Arterial blood pressure, cardiac index, systemic vascular resistance,

peripheral tissue oxygenation, cerebral oxygen saturation, buccal

microcirculation.

Secondary outcome

NA

Study description

Background summary

In ophtalmic surgery the specific anaesthesiological challenges necessitate the administration of a combination of relatively high doses of hypnotics and analgetics. In order to preserve adequate organ perfusion, there is often a need to administer pharmacological agents for haemodynamic support. Depending on the experience of the anaesthetist a continuous infusion of phenylephrine or norepinephrine is used. It is currently not known which of these agents has the most favorable haemodynamical profile.
Haemodynamic parameters (continuous blood pressure, cardiac index, stroke volume and systemic resistance), peripheral tissue oxygenation and cerebral tissue oxygenation will be monitored noninvasively using the Nexfin® , Inspectra®, and Foresight® and O2C® monitoring devices.

Study objective

Determine whether phenylephrine or norepinephrine has superior haemodynamical effects in ophtalmic surgery

Study design

randomized interventional prospective study

Intervention

Randomization between use of norepinephrine or phenylephrine for hemodynamic support

Study burden and risks

In this study, we will provide standard anaesthesia during standard clinical practice. Either phenylephrine or norepinephrine is routinely used as haemodynamical support in ophtalmic surgery, depending on the preference of the anaesthetist. Whether the patient will be treated with phenylephrine or norepinephrine will be randomly determined. All additional monitoring devices are noninvasive.
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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients undergoing ophtalmic surgery and requiring general anaesthesia.
withe:
-diabetes
-cardiovascular disease
>55 years
All patients: age > 18 years and older

Exclusion criteria

Patient refusal;- Patient < 18 years

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2011
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Norepinephrine CH
Generic name:	Norepinephrine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Phenylephrine
Generic name:	phenylephrine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-12-2011
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	EUCTR2011-004229-28-NL
CCMO	NL37997.042.11