Bayesian model-based versus Reinforcement learning closed-loop control of BIS guided propofol administration during intra-operative anesthesia.

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to compare the robustness of two existing closed-loop control technologies for BIS-guided propofol administration in combination with open-loop effect-compartment controlled remifentanil infusion. Robustness of the controllers will be evaluated and...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34212

Source
ToetsingOnline

Brief title
Bayesian model-based versus R.L. closed-loop anesthetic control

Condition

- Other condition

Synonym
closed loop control, computer program

Health condition

chirurgische ASA class I and II patienten die gehele narcose ondergaan

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anesthesia, Bayesian model, closed-loop control, Reinforcement learning

Outcome measures

Primary outcome

to compare the robustness of two existing closed-loop control technologies for BIS-guided propofol administration in combination with open-loop effect-compartment controlled remifentanil infusion. Robustness of the controllers will be evaluated and compared according to widely accepted laboratory performance criteria and peri-operative clinical outcome.

Secondary outcome

In the Bayesian controller, the time course of the Ce50 of propofol versus the CeRemi will be analyzed. In both controllers, hemodynamic stability during induction, maintenance and recovery will be compared between controller groups. Recovery times will be compared between groups.

Study description

Background summary

Propofol is the most frequently applied hypnotic-anesthetic iv drug during anesthesia. In *open-loop* controlled propofol administration during anesthesia, initial dosing guidelines are based on the typical subject, without taking into account the large inter individual variability. To manage this

variability, most clinicians will start by giving a standard dose, observes the therapeutic effect and will adapt the dose regimen. Although, *open-loop* drug administration is clinically *standard-of-care*, the efficiency of this decision process highly depends on the expertise of the clinician, is very time consuming and might result in a suboptimal therapy. This process of dose titration might be optimized by applying closed-loop drug administration techniques. Propofol closed-loop controllers are computer programs designed to maintain a targeted effect as defined by BIS by adapting the administered amount of drugs. In closed-loop control, the anesthesiologist only enters the desired variable to be maintained (*BIS target*). Previously, both groups at the University Medical Center Groningen (in collaboration with the Ghent University, Gent, Belgium, Demed Engineering, Temse, Belgium and Aspect Medical, Norwood, MA, USA) and Stanford University (in collaboration with Mr. Brett Moore, Department of Computer Science, Texas Tech University, Lubbock, TX, USA) have developed technologies for computer controlled drug administration being Bayesian model-based drug administration and Reinforcement learning (RL) controlled drug administration. For the Bayesian control, various publication in simulations and clinical practice has shown that safety and accuracy can be garantueed so far, however, more in depth study is required. For, the RL, simulation and preliminary volunteer research has been done.

Study objective

to compare the robustness of two existing closed-loop control technologies for BIS-guided propofol administration in combination with open-loop effect-compartment controlled remifentanil infusion. Robustness of the controllers will be evaluated and compared according to widely accepted laboratory performance criteria and peri-operative clinical outcome.

Study design

Prospective, double-blinded, randomized comparison study

Study burden and risks

The induction of anesthesia (until start of surgery) will be extended with 5 to 10 minutes for obtaining specific performance endpoints. We do not expect additional risk for the patient

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

Age > 18 years and < 65 years
ASA class I and II patients requiring general anesthesia for elective surgical procedures.

Exclusion criteria

patient refusal
ASA class > 2
BMI < 18 or > 29
allergy to one of the study medication
chronic pain
neurological disorder including CVA, stroke, etc*
recent use of psycho-active medication, including alcohol abuse
history of difficult airway management
documented liver and kidney disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-07-2010
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
CCMO	NL32021.042.10