The accuracy of a Bayesian-based, patient-individualized, pharmacodynamic advisory system to optimize propofol administration using the qCON index as a controlled variable. A comparison versus standard of care.

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To assess the accuracy of a Bayesian-based, patient-individualized, pharmacodynamic advisory system to optimize propofol effect-compartment-controlled administration using the qCON index as a controlled variable versus qCON-guided effect-compartment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON50457

Source
ToetsingOnline

Brief title
BIPAS - Bayesian-based propofol infusion advisory tool validation

Condition

- Other condition

Synonym
Narcosis, sleep medication

Health condition

Anesthesiologie bij operatieduur >1 uur

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Advisery Tool, Anesthesiology, Propofol, Target Controlled Infusion

Outcome measures

Primary outcome

The percentage of case time the qCON remains within +/- 10 units from targeted

qCON

Secondary outcome

* time until LOC from the start of propofol infusion and the amount of propofol

used during induction.

* The control performance during induction will be studied taking into account

the following parameters :

* qCONLOC = qCON at the moment of loss of consciousness .

* TqCON TARGET = observed time required for reaching the target qCON range

within +/- 10 units from targeted qCON.

* TPEAK, qCON = observed time required for reaching maximal drug effect (lowest

qCON value).

* qCONPEAK = observed qCON value at tPEAK, qCON.

* TEQ = observed time required for finally reaching the target range within +/-

10 units from targeted qCON with or without overshoot, also called time to

steady-state.

Study description

Background summary

Target-controlled infusion has been developed towards a mature technology routinely used in clinical practice to target plasma and effect-site concentration for drug infusion such as propofol, instead of volumetric infusion using inaccurate units per hour. The cerebral drug effect is routine measured by a *depth of anaesthesia monitor*, based on a processed EEG system, such as the qCON (Fresenius, Brésins, France). Nowadays, the anesthesiologist has to combine the independent information from the propofol effect-site concentration on the pump display and the qCON index from the EEG monitor to make an accurate decision in order to optimize drug administration. However, the effect-site concentration can be linked to effect as measured by qCON and can be modelled in an sigmoidal *E-max* curve. This could allow the clinician to observe the combined information in an advisory display.

As the relationship between effect-site concentration of propofol and qCON is dynamically and continuously changing over time, a computer algorithm could be helpful to personalise the sigmoidal *Emax* curve on the advisory display towards the individual patient and his/her condition (e.g. other drugs given simultaneously during propofol-based anesthesia). Adjusting predictions using prior information, based on measurements, could continuously update the E-max curve. This can be done by applying Bayesian-adjustment implemented in an advisory tool that provides dose titration advices for the clinician aiming to reach a corresponding preset desired qCON value in a continuous matter.

Study objective

To assess the accuracy of a Bayesian-based, patient-individualized, pharmacodynamic advisory system to optimize propofol effect-compartment-controlled administration using the qCON index as a controlled variable versus qCON-guided effect-compartment controlled propofol administration without the input of the advisory system.

Study design

Randomized-controlled trial for medical equipment (i.e. the new advisory tool)

In both groups, propofol administration will be executed by an anesthesiologist

or nurse anesthesiologist.

The advisory system display will be blinded in the control group (in order to obtain all data for post-hoc analysis).

Study burden and risks

Informed consent is obtained from all patients prior to randomization. During the case, the patients will be monitored according to routinely clinical standards, such as qCON, ECG, Non-invasive blood pressure (NIBP), Pulse Oximetry (SpO2). Each patient will receive a venous access in the non-dominant arm or hand for drug and fluid infusion as per clinical practice.

The administration of propofol following the advices of the Bayesian advisory tool would hypothetically lead to optimize patient care. As such, a benefit might be expected compared to standard clinical practice (less accumulation of drug, faster recovery from anaesthesia, less overshoot in propofol effect when dose adjustments are performed etc.).

Safety of the application of the Bayesian advisory tool is guaranteed by the fact that the
decision of dose adjustment remains under control of the anesthesiologist at all times during this study. It is up to this clinician to follow the advices given by the display system or not.

The risk of participating in this study is identical to the risk of the normal clinical procedure.

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

* 18 years or older
* American Society of Anesthesiology (ASA) Classification 1-4
* Elective surgery under general anaesthesia with propofol
* Surgery duration longer than one hour

Exclusion criteria

* The use of psycho-active drugs
* alcohol or recreative drug abuse.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2019
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	RUGLOOP II
Registration:	No

Ethics review

Approved WMO Date:	16-07-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-07-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL64961.056.18