Bayesian-based propofol infusion advisory tool validation

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29097

Source
Nationaal Trial Register

Brief title
BIPAS

Health condition

Anesthesiology, propofol infusion, target controlled infusion, medical advisory tool
Anesthesiologie, propofol toediening, medisch advies systeem

Sponsors and support

Primary sponsor: Medical University Center Groningen
Source(s) of monetary or material Support: Medical University Center Groningen

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• time until loss of consciousness (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 LOC.

• 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 between 40 and 60 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 and the clinical feasibility 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

Continues registration of required parameters for advisory tool from start of anesthesia induction till the end of propofol infusion.

Also, during recovery, we will compare the time from stop propofol infusion until opening of the eyes on command and orientation. Hereby, orientation will be defined as saying name and date of birth on request.

Intervention

target controlled propofol infusion with and without advisory tool.

Contacts

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Eligibility criteria

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:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2019
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6824
NTR-old	NTR7011
Other	UMCG Research Register : 201800065

Study results