Validation of the Eleveld propofol PKPD model

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23552

Source
NTR

Brief title
ELEVELD

Health condition

Anesthesiology, PKPD modeling

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Performance criteria (performance error, median (absolute) performance error, divergence, wobble) assessing the performance of the Eleveld PKPD model in the studied population.

Secondary outcome

na

Study description

Background summary

Target controlled infusion (TCI) of anaesthetic drugs such as propofol allows for more stable plasma concentrations or effect, and is a clinically applied technique for drug administration during general anaesthesia. TCI requires reliable pharmacokinetic (PK) or pharmacokinetic/pharmacodynamic (PKPD) models for the specific drug. For propofol, many PK(PD) models are available, but are developed from many different populations and from different study protocols. Extrapolation of such models may pose risks of under- and/or overdosing of patients. The Eleveld PKPD model was developed using available data from many of these studies. The population from which this model is derived, is therefore far broader than any existing models, and application of this model is theoretically also much broader. However, this model has yet to be validated in a separate study, which is the aim of this current study.

Study objective

The Eleveld propofol PKPD model allows administration of propofol by use of target controlled infusion (TCI) in a broad population (children-adults-elderly-lean-obese).

Study design

close to 5, 10, 20, 30, 40 and 60 minutes after start of propofol TCI.

If operation takes longer than 60 minutes, samples will be taken at 30 minute intervals, with a maximum of 10 samples in total.

Intervention

This is a validation study where patients from a broad population (age-range, lean and obese) receive TCI propofol using the Eleveld model. Blood samples will be taken to measure plasma concentrations of propofol and compared with predicted plasma concentrations. Bispectral index will be used as a surrogate measurement of propofol effect, and compared to predicted BIS and predicted effect-site concentrations.

Contacts

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Eligibility criteria

Inclusion criteria

- 3 years and older

- American Society of Anesthesiologists (ASA) physical status 1-4

- Elective surgical procedure with an expected duration of 1 hour or more.

- Need for an arterial line placement for the procedure

- Written informed consent

Exclusion criteria

- Contraindication for the use of propofol (i.e. allergy)

- Inclusion in other studies preventing the use of propofol as primary hypnotic agent

- Patients who have been admitted to the intensive care unit prior to surgery and/or have received propofol as sedation or anaesthesia in the 24 hours before the study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2018
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-04-2018
Application type:	First submission

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	NL6958
NTR-old	NTR7146
Other	UMCG Research Register number : 201800282

Study results