Validation of the Eleveld propofol PKPD model

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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).

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23552

Bron
Nationaal Trial Register

Verkorte titel
ELEVELD

Aandoening

Anesthesiology, PKPD modeling

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Hanzeplein 1
R. Spanjersberg

Groningen 9700 RB
The Netherlands
+31 (0)50 3611158

Wetenschappelijk

Hanzeplein 1
R. Spanjersberg
Groningen 9700 RB
The Netherlands
+31 (0)50 3611158

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2018
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	10-04-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6958
NTR-old	NTR7146
Ander register	UMCG Research Register number : 201800282

Resultaten