REAL-TIME BEDSIDE MONITORING OF BLOOD PROPOFOL CONCENTRATIONS:

Gepubliceerd: 15-05-2013 Laatst bijgewerkt: 18-08-2022

1) The aim of this study will be to prospectively test the validity of the Pelorus-Rapid-Propofol-Measurement-system (Sphere Medical) during TIVA anaesthesia. 2) Assesment of interference between propofol bloodconcentrations and sufentanil. 3)...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25330

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Blood propofol concentrations
Intrancranial neurosurgical intervention
ear surgery
Nociception
Influence of opioid supplementation

Ondersteuning

Primaire sponsor: Universitair Ziekenhuis Brussel
Laarbeeklaan 101
1090 Jette
Overige ondersteuning: Universitair Ziekenhuis Brussel
Laarbeeklaan 101
1090 Jette

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The aim of this study will be to prospectively test the validity of the Pelorus rapid propofol measurement system(Spere Medical) during TIVA anesthesia.

Toelichting onderzoek

Achtergrond van het onderzoek

A method to determine blood concentrations of propofol is desirable to improve the safety and adjust anesthetic depth. The ability to monitor the blood concentration of propofol in real time would allow us to better titrate and provide adequate anesthesia throughout a surgical procedure. While real time monitoring of inhaled anesthetic concentration is a standard of care there is until now no equivalent commercially available system for the measurement of propofol. Current validated methods of analysis are laboratory based assays requiring considerable time for sample preparation and analysis. These are suitable for population pharmacokinetic studies, but the slow turnaround time of such tests preclude there application to real time management of patients. Estimations of blood propofol concentration from expired gases has yet to demonstrate consistent and reliable results.
Sphere Medical (Cambridge UK) has introduced the Pelorus 1000 propofol measurement system, which has been designed for rapid analysis of propofol concentration in whole blood samples. A sample of 0.7 ml is required and the whole blood propofol concentration is determined in approximately 5 min. The measurement technology used in the Pelorus is based on quantitative colorimetric principle.
The system has been shown to fulfill the requirements for measurement of propofol concentration in whole blood samples with precision and accuracy suitable for elucidating propofol pharmacokinetics at clinical relevant concentration with no requirement for sample preparation and a fast time to results. The analysis offers the opportunity to study propofol blood concentrations in real time at the bedside of the patient

8-jun-2015: Changes in hypothesis, inclusion criteria, intervention, primary outcome, secondary outcome and timepoints.

Doel van het onderzoek

1) The aim of this study will be to prospectively test the validity of the Pelorus-Rapid-Propofol-Measurement-system (Sphere Medical) during TIVA anaesthesia.

2) Assesment of interference between propofol bloodconcentrations and sufentanil.

3) Assessment of gender influence on propofol concentration.

Onderzoeksopzet

Arterial blood samples for propofol concentration determinations will be taken at the following timepoints:

1) Baseline

2) After start propofol every 5' during first 15 minutes

3) Every 15' until 1 hour after induction

4) Every 30 minutes till two hours after end of propofol TCI

Onderzoeksproduct en/of interventie

Part I: A comparison of blood propofol concentrations during a TCI administration of a 1% or 2% formulation of propofol during intracranial neurosurgery/thyroid surgery/ear surgery
I.V. line for propofol and remifentanil/sufentanyl.
Remifentanil target controlled infusion Administration of remifentanil: set blood target Cp at desired concentration (0.2 ng/ml to start) or sufentanyl TCI (Start at 0,3ng/ml).

Administration of propofol: set target Cp at 4 µg/ml blood concentration. (Alaris PK pump, PK model Marsh/Schnider).

Intubation and ventilation.

During thyroid surgery, hypnotic effects are monitored using Neurosense monitoring (Neurowave systems) and propofol TCI is adapted to hold BIS between 40 and 60. Analgesic effects are monitored using A.N.I monitoring. Sufentanyl TCI is adapted to hold A.N.I. between 50 and 70.

During neurosurgery and ear/breast surgery, depth of anesthesia will be assessed by the haemodynamic and autonomic responses to surgical stimulation i.e.:

• An increase of systolic blood pressure > 20% from postinduction baseline value

• An increase of heart rate > 20% fom postinduction baseline value

Monitoring of vital signs (SBP, DBP, MAP, HR and SaO2). continue invasive blood-pressure and cardiac output will be assessed with the Flo-Trac (Edwards lifescience)

Part II: Influence of opioid supplementation with sufentanil or remifentanil on the real time blood concentrations of propofol during TCI.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Male and female non-pregnant patients scheduled for elective intracranial surgery, ear surgery or thyroid surgery with a minimal duration of at least 3 hours.

ASA Physical status I or II

Age between 18-75 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Serious impairment of respiratory, cardiovascular, hepatic, renal, haematopoetic or endocrine function.
Known allergy to propofol or constituents (Soya-bean-eggs).

Previous adverse experience of general anaesthesia.

Pregnancy.

More than 50% under or above ideal weight.
History of opioid drug abuse or alcohol addiction.

Concurrent use of beta-blockers

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-05-2013
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-05-2013
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	NL3807
NTR-old	NTR3995
Ander register	MEC UZ Brussel : 2013/083
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A