

Clinical comparison between two propofol pumps for general anaesthesia

Submission date 30/09/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/11/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

General anaesthesia can be delivered by intravenous drugs such as Propofol. In recent years various methods have been proposed to estimate the concentration in blood and at the brain (effector site) of this drug, utilizing pharmacokinetic and pharmacodynamic calculations. Eleveld and Schnider model are 2 of the Propofol model most commonly used in the clinical practice to deliver Propofol for general anaesthesia, however, their accuracy in predicting concentrations are different. The aim of this study is to evaluate if there are differences in estimating concentrations at loss of consciousness, return of consciousness and during general anaesthesia, as well as to compare if superficliazation or deepening events incidence is different between the 2 models, during Bispectral Index guided anesthesia.

Who can participate?

Adult women undergoing general anesthesia with TCI, undergoing breast surgery.

What does the study involve?

The procedure will proceed as usual, using TCI pumps with Eleveld and Schnider models

What are the possible benefits and risks of participating?

None

Where is the study run from?

Azienda ULSS 2 Treviso (Italy)

When is the study starting and how long is it expected to run for?

October 2022 to December 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

280922

Study information

Scientific Title

Schnider versus Eleveld propofol target controller infusion model: a clinical comparison evaluating concentration at the effector site of propofol at loss of responsiveness during anesthesia maintenance and return of responsiveness

Study objectives

During recent years Eleveld and colleagues ideated a new propofol pharmacokinetic /pharmacodynamic (PK/PD) model for total intravenous anaesthesia with target controlled infusion (TIVA-TCI) pumps that has been proposed to have slightly better predictive performance for measured propofol plasma concentrations compared with those of the Marsh and Schnider models, and suitable for children, adults, older subjects, and obese adults, being considered as a "General purpose" model.

However, no trials have compared the Eleveld to the Schnider model from a clinical point of view; so, this study aimed to compare the estimated effector site concentration of the two models (CePE and CePS, respectively) at loss of responsiveness (LoR), during anaesthesia maintenance (Bispectral Index [BIS] 40-60) and return of responsiveness (RoR). The study also compared the incidence of deepening or superficializing anaesthesia (defined respectively as

lowering or increasing in out-of-target BIS after initial CeP detection), as well as unwanted anaesthesia events: burst suppression (BSupp, identified as a burst suppression ratio [BSR] >0) and unwanted spontaneous responsiveness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/01/2022, comitato etico di Treviso-Marca trevigiana (ospedale va Foncello, piazza ospedale 1, Treviso, Italy; +39 422328306; nrcaulss9@aulss2.Veneto.it), ref: 681/CE

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

General anaesthesia

Interventions

This study will enrol 78 patients who are undergoing breast oncologic surgery. Estimating the mean and standard deviation (SD) from the median and range of the Median Absolute Performance Error (MAPE) between the Eleveld PK-PD model and the Schnider PK-PD model in adults, the sample size was based on the following assumptions: a significant MAPE difference of 4% between the Eleveld PK-PD model and the Schnider PK-PD model in adults, an SD of 6.3%, type I error equal to 0.05, and type II error equal to 0.2 (power $[1-\beta] = 0.8$). Considering these assumptions, the sample size was calculated as 78 patients, equally divided between the Eleveld PK-PD model group (39 patients) and the Schnider PK-PD model group (39 patients).

Induction and maintenance of anaesthesia were performed with TIVA-TCI. CeP and Ce of remifentanyl (CeR) were achieved using the uSP6000 syringe pump infusion system (Arcomed ag, Steineckerstrasse 29 CH-8302 Kloten (Switzerland) using the Schnider or Eleveld model for Propofol, and Minto for remifentanyl.

After standard vital parameters monitoring including also Bispectral Index (BIS) using an XP monitor (Monitor BIS Module A-2000 Revision 3.12) with a bilateral electrode BIS (Covidien IIC, 15 Hampshire Street, Mansfield, MA 02048 USA) on the forehead of the patient, induction was started according to our hospital protocol, setting a CeP target of 0.5 $\mu\text{g ml}^{-1}$, with increments

of 0.5 µg ml⁻¹ intervals when the estimated CeP equilibrated with target CeP. CeR was settled at 0.8 ng ml⁻¹ until LoR (defined as loss of responsiveness to verbal commands), when both CeP and CeR were placed at 3 µg ml⁻¹ and 3 ng ml⁻¹, respectively. Then, a laryngeal mask Airways (LMA) was placed. During anaesthesia maintenance, CeP was adjusted to a target BIS of 40–60 by changes of 0.5 µg/ml at intervals of ≥1 min until BIS returned to the suggested range. The initial CeP during maintenance was defined as the CeP reached after a stable BIS for >10 minutes without CeP target changes. According to the protocol, if during maintenance the patient manifested any out-of-target BIS, the researchers set a new target concentration that, once the BIS returns in range for >10 minutes, was registered as final CeP. At the end of surgery, TIVA-TCI was targeted to a CeP of 0 µg/ml and a CeR of 0 ng/ml. With the return of spontaneous ventilation at RoR, defined as spontaneous eye-opening and execution of simple commands, the LMA was removed.

Intervention Type

Other

Primary outcome measure

1. Concentration of propofol at loss of consciousness, return of consciousness and during maintenance measured using the display on the equipment
2. Occurrence of deep or light anesthesia during the procedure measured using EEG

Secondary outcome measures

Measured during the procedure measured using EEG:

1. Episodes of deepening anesthesia (BIS <40)
2. Superficializing anesthesia (BIS >60)
3. Burst suppression
4. Unwanted spontaneous responsiveness

Overall study start date

20/01/2022

Completion date

25/12/2022

Eligibility

Key inclusion criteria

Women undergoing general anesthesia with TIVA-TCI for breast surgery

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

78

Key exclusion criteria

1. Patients with any neurologic/respiratory/liver/kidney diseases
2. Patients taking any psychiatric drugs, including benzodiazepines

Date of first enrolment

30/10/2022

Date of final enrolment

25/12/2022

Locations**Countries of recruitment**

Italy

Study participating centre

Azienda ULSS2 Marca Trevigiana

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Sponsor information**Organisation**

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Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/10/2023	18/11/2024	Yes	No