Population pharmacokinetics/pharmacodynamics of Propofol in morbidly obese patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31661

Source
ToetsingOnline

Brief title
POP

Condition

- Other condition

Synonym
morbid obesity, obese

Health condition

morbide obesitas

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Obese, Pharmacodynamics, Pharmacokinetics, Propofol

Outcome measures

Primary outcome

The main objective is to develop a pharmacokinetic model of Propofol when used for induction and maintenance of anaesthesia in the morbidly obese patient.

Primary endpoints: pharmacokinetic parameters; clearance, intercompartmental clearance, volume of central compartment and volume of peripheral compartment.

Secondary outcome

The secondary objective is to develop a pharmacodynamic model of Propofol when used for induction and maintenance of anaesthesia in morbidly obese patients.

Secondary endpoints: pharmacodynamic parameters; time to induction of anaesthesia (stop counting, eyelash reflex, quality of anaesthesia, corresponding dose required for induction of anaesthesia for both induction doses), EC50 using BIS, required doses of Propofol during maintenance of anaesthesia, wake-up time.

Study description

Background summary

The extreme increase of obesity in the last years had led to this study. There is no consensus about how to anaesthetise morbidly obese patients. The amounts of narcotics given vary widely and rather depend on the anaesthetist than on

the pharmacokinetics and dynamics in the morbidly obese patient. Reason for this is that it is not clear in what extend the pharmacokinetics and dynamics are affected in the morbidly obese patient.

Study objective

The study is performed in order to develop a population pharmacokinetic and pharmacodynamic model of Propofol when used for induction and maintenance of anaesthesia in the morbidly obese patient (BMI > 40). A covariate analysis will be performed in order to account for variability in pharmacokinetic and/or pharmacodynamic parameters. This model will take into account patient and procedure bound covariates. The results will be used to develop individualised dosing schemes of Propofol when used for induction and maintenance of anaesthesia in morbidly obese patients.

Study design

A randomised, therapeutic and non-invasive study.

Intervention

Patients will be randomised into two groups, one group will be given 200 milligrams of Propofol and the other group will be given 350 milligrams of Propofol. During the induction of anaesthesia with Propofol over 60 seconds, the patient is asked to count in order to measure time to induction of anaesthesia. During and following anaesthesia blood samples will be taken from an indwelling arterial line with a maximum amount of 50 ml.

Study burden and risks

A maximum amount of 50 milliliters of blood will be sampled from an indwelling arterial line. The patient will be asked to count slowly during induction of anaesthesia. Both induction doses of 200 and 350 milligrams are currently used standard induction doses for morbidly obese patients.

Contacts

Public
Selecteer

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1073 CD Amsterdam
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Scientific

Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Morbidly obese patients with a Body Mass Index > 40 undergoing laparoscopic banding or gastric bypass surgery, 18-60 year old.

Exclusion criteria

Epilepsy, pregnancy, breastfeeding and known allergy for Propofol, egg lecithin or soy bean oil.

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2007
Enrollment:	26
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Diprivan
Generic name:	Propofol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-04-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	04-06-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	26-03-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2006-005670-45-NL
CCMO	NL13980.100.06