THE PHARMACOKINETIC AND PHARMACODYNAMIC INTERACTION BETWEEN PROPOFOL AND KETAMINE WHEN GIVEN FOR SEDATION AFTER CARDIAC SURGERY IN THE INTENSIVE CARE UNIT.

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1. To quantify the influence of propofol on the distribution, redistribution and elimination of ketamine and to evaluate the importance of hemodynamic parameters on the pharmacokinetics of ketamine.2. To quantify the influence of ketamine on the...

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

Summary

ID

NL-OMON34050

Source
ToetsingOnline

Brief title
Propofol - ketamine interaction after cardiosurgery in the ICU

Condition

- Other condition

Synonym
eris geen sprake van een te bestuderen aandoening

Health condition

sedativum op IC na cardiochirurgische ingreep

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: interaction, ketamine, propofol, sedation

Outcome measures

Primary outcome

• Ramsay score

• BIS score

• Cardiac Output (Vigileo)

• Cardiac Index (Vigileo)

• RRsys

• RRdias

• MAP

• CVP

• HR

• SVV

• SVR

• Saturation

Secondary outcome

Concentration of propofol and ketamine from the several blood draws.

Study description

Background summary

propofol and ketamine may well be a promising anesthetic combination for sedation of patients after cardiac surgery (coronary artery bypass grafting (CABG) and aortic valve surgery) in the ICU. This study aims to evaluate the interaction between these 2 agents with respect to their pharmacokinetics (distribution, redistribution and elimination) and pharmacodynamics (sedation, hemodynamic side effects and attenuation of the inflammatory response) in patients after cardiac surgery.

Study objective

1. To quantify the influence of propofol on the distribution, redistribution and elimination of ketamine and to evaluate the importance of hemodynamic parameters on the pharmacokinetics of ketamine.

2. To quantify the influence of ketamine on the distribution, redistribution and elimination of propofol and evaluate the importance of hemodynamic parameters on the pharmacokinetics of propofol.

3. To evaluate the pharmacodynamic interaction between propofol and ketamine with respect to the sedative and hemodynamic effects during sedation in patients sedated in the ICU.

Study design

randomised single blind follup study

Intervention

During study A, 21 ICU patients will be sedated using a target controlled infusion of propofol at one of 3 fixed target propofol concentrations in addition to a target controlled infusion of S(+) ketamine with a variable target ketamine concentration to assure adequate sedation to a Ramsay sedation score of 4. During study B, ICU 21 patients will be sedated using a target controlled infusion of S(+) ketamine at one of 3 fixed target ketamine concentrations in addition to a target controlled infusion of propofol with a variable target propofol concentration to assure adequate sedation to a Ramsay sedation score of 4. Meanwhile several hemodynamic en neurological parameters will be recorded and several blood draws will be performed to measure propofol and ketamine concentrations.

Study burden and risks

No extra risk apart from the standard risk after cardiac surgery and the risk of drawing a maximum of 150ml of blood during 6 hours in the post-operative phase.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Scheduled for ventilation and sedation at the ICU post cardiac surgery.
Aged 18-80 years.
Being able to give written informed consent.

Exclusion criteria

Unable to give written informed consent.
Increased intracranial pressure
Poor ventricular function
Epilepsy
Psychosis
Glaucoma
History of cerebrovascular incident < 1 year
Pregnancy
Documented or suspected soybean protein and/or drug allergy.
Morbid obesity (BMI > 35).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	42
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ketanest-S
Generic name:	S+Ketamine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Propofol-Lipuro

Generic name:	Propofol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-07-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-09-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27257
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2010-021484-32-NL
CCMO	NL32985.058.10
OMON	NL-OMON27257