Ketanest in Intensive Care Unit Patients

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Compare induction of anaesthesia using etomidate versus ketanest on hemodynamics, as well as microcirculatory consequences in patients admitted to the ICU and in need of ventilatory support.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON35229

Source
ToetsingOnline

Brief title
KICUP

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
coma, respiratory failure

Health condition

intensive care patiënten waarbij inductie van anesthesie geïndiceerd is

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: geld vanuit eigen fonds) intensivisten

onderzoeksgroep CWZ;dus eigen middelen.

Intervention

Keyword: Etomidate, Ketanest, Microcirculation, Near-infrared spectroscopy

Outcome measures

Primary outcome

CVP (10 min average)

HR/BP (10 min average)

MAP (10 min average)

Urine output (60 min average)

Resuscitation volume (specific sum)

Inotropic support (value of rate and cumulative dose)

Vasopressor support (value of rate and cumulative dose)

Microcirculatory function

Secondary outcome

Ventilatory and oxygen delivery variables

Adverse psychological reactions

Study description

Background summary

Until recently, most anaesthetists and intensivists used etomidate as induction agent for anaesthesia in cardiorespiratory compromised patients admitted to the intensive care unit (ICU), because of its favourable effect on cardiovascular stability. However, awareness of the adverse effects of a single induction dose of etomidate on the adrenal gland has increased over the last decade. Alternatively, ketanest can be used as an induction agent, probably with comparable effects concerning macrocirculatory stability, but without suppressing the adrenal gland. Therefore, induction of anaesthesia using

ketanest in critically ill patients may be superior compared to etomidate. However, the effect of ketanest on the microcirculation is -until now- unknown.

Study objective

Compare induction of anaesthesia using etomidate versus ketanest on hemodynamics, as well as microcirculatory consequences in patients admitted to the ICU and in need of ventilatory support.

Study design

Prospective single-centre observational study.

Intervention:
Patients accepted for this study are alternately allocated to either the ketanest (K) or etomidate (E) group. Anaesthesia is induced with either ketanest (1 mg/kg) (K group) or etomidate (0.3 mg/kg) (E group). Sedation is maintained with midazolam (10 mg/h) and morphine (2 mg/h) in both groups. For the measurements of the microcirculatory consequences, short vascular occlusions will be applied immediately prior to induction and at 5-10-15-20-30-45-60-90-120-150-180-210 and 240 minutes after induction.

Study burden and risks

Etomidate is a commonly used induction agent with cardiovascular stability and adrenal gland suppression.

Ketanest is an anaesthetic induction agent with analgesic effects and usually without depression of the cardiovascular and respiratory system.

NIRS is a noninvasive patient-friendly optical technique that uses near-infrared light of low intensity and is completely harmless. This device has frequently been used in an ICU setting as well as in healthy volunteers.

Vascular occlusion. NIRS will be used in combination with a manually applied vascular occlusion. Application of vascular occlusion is short (1 min) and the pressure used is comparable with the pressure used for a standard blood pressure measurement or the occlusion applied for a routine venapunction. Although the occlusion might be experienced as unpleasant or might cause temporary pain, both are reversible and no damage will be done to the tissue. Similar methods, with even longer occlusion time, have been used previously in many studies including several in patients admitted to the ICU (for review see Gerovasili, 2010).

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

Patients in an intensive care unit:
1. in need for ventilatory support.
2. to be intubated on the ICU.

Exclusion criteria

1. <18 years old.
2. symptomatic coronary artery disease.
3. due to have surgery within 3 hours.
4. already on corticosteroid therapy
5. pregnancy.

6. pulmonary hypertension.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	24-01-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL37999.091.11