Ketanest in septic shock.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28809

Source
Nationaal Trial Register

Brief title
KISS

Health condition

Patients in need for intubation in early septic shock.

Sponsors and support

Source(s) of monetary or material Support: departemental funding

Intervention

Outcome measures

Primary outcome

These variables are measured every hour during the first 8 hours. However, these variables will be measured every 10 minutes during:

1. The two hour following the induction of anesthesia (0-2h);

2. The two hour after the switch to midazolam/fentanyl anesthesia (2-4).

1. CVP (10 min average);

2. HR/BP (10 min average);

3. MAP (10 min average);

4. Urine output (60 min average);

5. ScvO2 and arterial blood analysis (every 30 minutes);

6. Resuscitation volume (specific sum);

7. Inotropic support (value of rate and cumulative dose);

8. Vasopressor support (value of rate and cumulative dose).

Secondary outcome

1. Ventilatory and oxygen delivery variables:
Airway pressures / FiO2 / tidal volume / Lactate /Hb, are measured every hour during the first 4 hours, and after 8 hours;

2. Adverse psychological reactions:
During the observation period, checking the medical record upto 24 hours after induction, and, if possible, asking the patient for adverse psychological effects as soon as possible after awaking and after extubation;

3. Adrenal gland responsiveness:
Before induction: basal serum total cortisol, free cortisol, and 11beta-deoxycortisol
At 6 and 24 hrs after induction of anesthesia: basal serum total cortisol, free cortisol, and 11beta-deoxycortisol followed by a standard high dose (250 ug of synthetic ACTH) Synacthentest, with measurements of total, free cortisol and 11-beta deoxycortisol at 0, 30 and 60 minutes;

4. Inflammatory markers:
Baseline, 6 and 24 hours: IL6, TNFa.

Study description

Background summary

Rationale:
In patients with septic shock, most anesthetists are used to induce anesthesia with etomidate, because of its favourable effect on cardiovascular stability. However, awareness

of the adverse effects of single induction dose of etomidate on the adrenal gland, and the hemodynamic advantages of ketanest have increased over the last decade. Therefore, induction of anesthesia using ketanest in critically ill patients may be superior compared to etomidate.

Objective:
Compare induction of anesthesia using etomidate or ketanest on hemodynamic consequences and adrenal function in patients with septic shock in need of intubation.

Study design:
prospective single center randomized not-blinded clinical trial.

Study population:
patients admitted to the ICU with septic shock and in need of ventilatory support.

Intervention:
anesthesia is induced with ketanest (1 mg/kg) in the trial group (K), and with etomidate in the control group (E). Sedation is maintained with ketanest (1 mg/kg/h) in the K group and midazolam (10 mg/h) and fentanyl (0.1 mg/h) in the E group during the first 2 hours.

Main study parameters/endpoints:
The primary outcome variables reflect hemodynamics during the first two hours after induction, and following the switch to standard sedation. The secondary outcome variables reflect organ function, the extent of adrenal gland suppression following induction of anesthesia and assessment of psychological side effects.

Study objective

We hypothesise that (restoration of) a adequate circulation in early septic shock is reached sooner and with less vasoactive support and fluid therapy using ketanest.

(Secondary): Furthermore, we hypothesise that adrenal gland is not suppressed following induction of anesthesia with ketanest, in contrast to induction with etomidate.

Study design

25 hours after induction of anesthesia the observation (study) period ends.

Intervention

Investigational treatment.

Patients accepted for this study are randomised to either the ketanest (K) or etomidate (E) group. The only a priori difference in treatment will be the induction and maintenance agent. The K protocol demands induction with ketanest (1.0 mg/kg) and rocuronium 1.2 mg/kg, followed by maintenance with ketanest (1-3mg/kg/h). The E group is induced with etomidate 0.2 mg/kg and rocuronium 1.2 mg/kg, followed by maintenance with midazolam (4-10 mg/h) and fentanyl (100ug/h). Maintenance doses must be adjusted to individual need.
Two hours after induction of anesthesia (i.e. start of the intervention) maintenance with ketanest will be switched to midazolam and fentanyl. Sedation with midazolam and fentanyl must be continued for at least 23 hours in order to prevent adverse psychological effects.

Contacts

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Eligibility criteria

Inclusion criteria

1. Septic shock (see below);

2. In need for ventilatory support;

3. To be intubated on the ICU.

Exclusion criteria

1. <18 and >80 years old;

2. Symptomatic coronary artery disease;

3. Due to have surgery within 4 hours;

4. Already on corticosteroid therapy;

5. Pregnancy;

6. Pulmonary hypertension;

7. Preterminal illness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-02-2009
Application type:	First submission

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
NTR-new	NL1592
NTR-old	NTR1672
Other	ABR/EudraCT : 22992/2008-002598-11
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A