

A comparison of two sleep induction drugs used in the intensive care

Submission date 23/03/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/03/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 18/09/2014	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Endotracheal intubation is a medical procedure in which a tube is placed into the windpipe (trachea), through the mouth or the nose. It is a routine emergency procedure in intensive care. For this procedure it is usual to make the patient asleep, and for this purpose several drugs are available. Several drugs have adverse effects on blood pressure. However, blood pressure remains stable after the use of etomidate, therefore etomidate is a preferable drug for sick and unstable patients. However, it has been suggested that a single dose of etomidate can be detrimental for the patient, resulting in higher mortality (death rate). The aim of this study was to compare the safety of etomidate with another drug, S-ketamine, well known for its blood pressure stability.

Who can participate?

Adult patients in the intensive care department who needed endotracheal intubation in order to start mechanical ventilation.

What does the study involve?

Participants underwent endotracheal intubation, with each patient receiving either etomidate or S-ketamine. The consequences of the two drugs were compared in terms of mortality within 28 days and blood cortisol levels.

What are the possible benefits and risks of participating?

A disadvantage of S-ketamine are the nasty dreams, which can occur in some patients. To avoid these dreams, S-ketamine was combined with a small dose of midazolam.

Where is the study run from?

Atrium Medisch Centrum (Netherlands).

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

The study started in April 2008 and lasted until December 2009.

Who is funding the study?

Atrium Medisch Centrum (Netherlands).

Who is the main contact?

Dr Cornelis Punt
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

11-N-94

Study information

Scientific Title

Etomidate and S-ketamine for endotracheal intubation in the intensive care: a prospective, open study

Study objectives

The safety of and the mortality after a single dose of etomidate and S-ketamine, used in the intensive care unit, are equal.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of the Atrium Medical Centre (METC) (Medisch Ethische Toetsingscommissie METC - Atrium - Orbis - Zuyd), ref: 11-N-94

Primary study design

Interventional

Study design

Prospective open study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Endotracheal intubation

Interventions

Routine procedure, endotracheal intubation.

Each patient received one of the following drugs:

1. Etomidate 0.2 - 0.3 mg/kg

2. S-Ketamine 0.5 mg/kg

These drugs were used to make the patients sleep before endotracheal intubation, which is an emergency procedure in the intensive care.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Etomidate, S-ketamine

Primary outcome(s)

Mortality within 28 days

Key secondary outcome(s)

Cortisol levels

Completion date

31/12/2009

Eligibility

Key inclusion criteria

Adult patients admitted in the intensive care department

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Younger than 18 years
2. Having received etomidate less than 72 hours before

Date of first enrolment

01/04/2008

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Ayrium Medisch Centrum

Heerlen

Netherlands

6401 CX

Sponsor information

Organisation

Atrium Medisch Centrum (Netherlands)

ROR

<https://ror.org/0367sy10>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Atrium Medisch Centrum (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration