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

Submission date
23/03/2012

Recruitment status
No longer recruiting

Registration date
30/03/2012

Overall study status
Completed

Last Edited
18/09/2014

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Prospective open study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Mortality within 28 days

Secondary outcome measures
Cortisol levels

Overall study start date
01/04/2008

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Adult patients admitted in the intensive care department

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
718 patients

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
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Sponsor information

Organisation
Atrium Medisch Centrum (Netherlands)

Sponsor details

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0367sye10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Atrium Medisch Centrum (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration