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Sleep quality in critically ill patients on proportional assist ventilation with load-adjustable gain factors (PAV+) vs pressure support (PS)

Submission date
22/10/2009

Registration date
11/11/2009

Last Edited
11/11/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Sleep quality in critically ill patients on proportional assist ventilation with load-adjustable gain factors (PAV+) vs pressure support (PS) - a randomised controlled cross-over trial

Study objectives
Previous studies have repeatedly reported sleep disruption in intensive care unit (ICU) patients with reduced nocturnal sleep efficiency and reduced slow wave and rapid eye movement sleep. Critical illness itself, the ICU environment, medications, and patient-ventilator interactions may all be contributing factors to altered sleep architecture. Alteration of sleep quality and quantity can have significant adverse consequences prolonging mechanical ventilation and ICU stay.

Proportional assist ventilation (PAV) is a mode of support during which the ventilator pressure is proportional to instantaneous flow and volume and hence to pressure generated by the respiratory muscles. The necessity of regular measurements of respiratory system mechanics imposes a major obstacle on the use of this mode. A software has been developed (PAV+) which automatically adjusts the flow assist (cmH2O/L/sec) and volume assist (cmH2O/L) such as to represent always constant fractions of the measured values of resistance and elastance of the respiratory system6 by applying a 300 msec pause maneuver at random intervals at the end of selected inspirations. It was recently shown that these brief end-inspiratory occlusions do not affect sleep quality or sedation requirements in a selected group of critically ill patients.

Parthasarathy and Tobin observed greater sleep fragmentation in critically ill patients during pressure support (PS) than during assist-volume control ventilation with backup rate. Numerous studies have shown that compared to PS, PAV improves the synchrony between patient and ventilator and may thus decrease sleep disruption and improve sleep quality. The aim of this study will be to compare sleep quality under constant conditions in critically ill patients ventilated with PAV+ and PS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, University Hospital of Heraklion Crete, approved on 12/12/2006 (ref: 13449)

Study design
Randomised controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Sleep quality in critically ill patients on mechanical ventilation

Interventions
Patients will be connected to an ICU ventilator (Puritan-Bennett® 840), able to ventilate them with PS and PAV. Polysomnography will be performed in each patient as previously described for 24 hours starting 10 PM in single rooms in the intensive care unit with the window blinds closed. During the study day patients will be ventilated randomly either on pressure support or on PAV+ mode. The pressure support at which the patient was ventilated before the study will serve as baseline pressure support. With PAV+ the percentage of unloading will be set such as to achieve a mean inspiratory airway pressure similar to that with baseline pressure support. In the 24-h study period patients will be ventilated for six 4-h periods (10PM-2AM, 2AM-6AM, 6AM-10AM, 10AM-2PM, 2PM-6PM, 6PM-10PM), three 4-h periods with PS, and three with PAV+. Each patient will be initially randomised to receive 4 hours of either PS or PAV+ followed by alternating 4-h periods of PS and PAV+.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Effect of PAV and PS in sleep quality.

Secondary outcome measures
Patient - ventilator interaction during sleep. Flow (V), volume (V), airway pressure (Paw), end-tidal CO2 (PETCO2), the motion of the rib cage and abdomen, inspiratory (TI) and expiratory (TE) time, total respiratory cycle time (TTOT) and peak inspiratory airway pressure (Pawpeak) will be measured on a breath-by breath basis, while coefficient of variation of tidal volume (VT) and TTOT will be calculated.

Overall study start date
25/10/2009

Completion date
30/03/2010

Eligibility

Key inclusion criteria
Critically ill patients (>18 years old, both males and females) who are receiving mechanical ventilation for at least 48 hours will be studied. At the time of the study all patients will be haemodynamically stable and ventilated on PS through cuffed endotracheal or tracheostomy

tubes with anticipated further mechanical ventilation of at least 24-h duration. All patients must achieve a score of 0 on the Richmond Agitation Sedation Scale (RASS) either with or without intravenous (IV) propofol.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Anticipated ICU stay <24 h
2. Premorbid diseases that could confuse interpretation of sleep monitoring including central nervous system (CNS) diseases and sleep disorders
3. Haemodynamic instability (BP <90 mmHg despite therapy)
4. Glasgow Coma Scale <11 and acute physiology score >13
5. General anesthetic, drug overdose, or alcohol intoxication within the preceding 24 h

Date of first enrolment
25/10/2009

Date of final enrolment
30/03/2010

Locations

Countries of recruitment
Greece

Study participating centre
Intensive Care Unit
Heraklion
Greece
71110

Sponsor information

Organisation
Cretan Critical Care Society (Greece)

Sponsor details
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Sponsor type
Research organisation

Website
http://icuheraklion.gr/index.html

Funder(s)

Funder type
Research organisation

Funder Name
Cretan Critical Care Society (Greece)

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