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Proportional Assist Ventilation with adjustable gain factors versus Pressure Support ventilation in critically ill patients

Submission date 15/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/10/2006	**Overall study status** Completed	
Last Edited 30/10/2008	**Condition category** Respiratory	

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

Acronym
PAV vs PS

Study objectives
To access the success rate and efficacy of Proportional Assist Ventilation (PAV) with adjustable gain factors versus Pressure Support (PS) in critically ill patients receiving controlled mechanical ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Heraklion University Hospital (reference number: 6122), date of approval: 30 /05/2006.

Study design
Randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory disorders requiring mechanical ventilation

Interventions
After enrolment PAV with adjustable gain factors or pressure support will be instigated and the patients will be monitored during the following 48 hours. Patients who meet any of the predefined failure criteria during this period are returned to controlled mechanical ventilation.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. PAV success rate
2. Sedation doses

Secondary outcome measures
1. Weaning time
2. Intensive Care Unit (ICU) mortality
3. Hospital mortality

Overall study start date
30/05/2006

Completion date
01/03/2008

Eligibility

Key inclusion criteria
1. Critically ill patients receiving control mechanical ventilation for at least 36 hours
2. Partial Pressure of Oxygen in Arterial Blood (PaO2) more than 65 mmHg, Fraction of Inspired Oxygen (FiO2) less than 65% and Positive End Expiratory Pressure (PEEP) level less than 15 mmHg
3. No respiratory distress

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Aged over 18 and under 85 years
2. Severe haemodynamic instability
3. Pregnancy
4. Neuromuscular disorders
5. End stage disease
6. Severe bronchospasm, resistance of the respiratory system more than 20

Date of first enrolment
30/05/2006

Date of final enrolment

01/03/2008

Locations

Countries of recruitment
Greece

Study participating centre
Intensive Care Unit
Heraklion
Greece
71110

Sponsor information

Organisation
Cretan Critical Care Society (Greece)

Sponsor details
Intensive Care Unit
Heraklion University Hospital
Voutes
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Sponsor type
Hospital/treatment centre

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	8 results	01/11/2008		Yes	No