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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

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 Heraklion Greece 71110 georgop@med.uoc.gr

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