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Automatic versus manual pressure support reduction in the weaning of post-operative patients: a randomised, controlled trial

Submission date 22/06/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/07/2008	**Overall study status** Completed	
Last Edited 12/03/2010	**Condition category** Surgery	

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

Study objectives
Weaning with mandatory rate ventilation is as fast and secure as the manual decrement of pressure support ventilation during a weaning trial in the post-operative intensive care unit (ICU) mechanically ventilated patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. The Ethical Committee of Albert Einstein Hospital on the 29th July 2002 (ref: 61/02)
2. The Ethical Committee of São Paulo Medical School (University of São Paulo-Brazil) in July 2006 (ref: 372/06)

Study design
Prospective, randomised, controlled clinical 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
Weaning from mechanical ventilation

Interventions
To compare two methods of weaning from mechanical ventilation: manual reduction of pressure support (every thirty minutes) versus automatic and computerised method (mandatory rate ventilation) in post-operative mechanically ventilated adult ICU patients.

The total duration of the weaning trial was 205 +/- 181 minutes (30 to 840 minutes) for the manual group and 157+/- minutes (30 to 545 minutes) for the automatic group. The patients were followed up for 48 hours after extubation.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Duration of weaning process.

Timepoints:
1. Start of ventilator triggering by the patient
2. Patient extubation

Secondary outcome measures
1. Levels of pressure support, from the start of spontaneous breathing till extubation
2. Respiratory rate, from the start of spontaneous breathing till extubation
3. Tidal volume, from the start of spontaneous breathing till extubation
4. Respiratory rate/tidal volume (L), from the start of spontaneous breathing till extubation
5. Fraction of inspired oxygen (FIO2), positive end expiratory pressure (PEEP) levels and oxygen saturation during the weaning process, from the start of spontaneous breathing till extubation
6. Need of re-intubation or need of non-invasive ventilation after 48 hours of extubation

Overall study start date
01/08/2002

Completion date
01/01/2004

Eligibility

Key inclusion criteria
Adult (more than 18 years old, either sex) mechanically ventilated post-operative ICU patients.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Haemodynamic instability
2. Neurological surgeries
3. Previous pulmonary disease

Date of first enrolment
01/08/2002

Date of final enrolment
01/01/2004

Locations

Countries of recruitment
Brazil

Study participating centre
Av. Albert Einstein 627- 5 andar
São Paulo
Brazil
05651-901

Sponsor information

Organisation
Albert Einstein Hospital (Brazil)

Sponsor details
Av. Albert Einsten 627 -5 andar
São Paulo
Brazil
05651-901

Sponsor type
Hospital/treatment centre

Website
http://www.einstein.br

ROR
https://ror.org/04cwrbc27

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Albert Einstein Hospital (Brazil) - Human Resources

Funder Name
Air Liquide Brasil Ltda (Brazil) - Taema HORUS Ventilator, lent for 2 years

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	results	01/01/2009		Yes	No