

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/03/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Carmen Barbas

Contact details

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

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Duration of weaning process.

Timepoints:

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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