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The use of non-invasive ventilation immediately after extubation to improve the weaning outcome in acute respiratory failure

Submission date 11/08/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/08/2008	**Overall study status** Completed	
Last Edited 19/03/2013	**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

Study information

Scientific Title
Efficacy of non-invasive positive pressure ventilation to prevent re-intubation and to improve hospital mortality after weaning in acute respiratory failure: a randomised, prospective study

Study objectives

Early application of non-invasive positive pressure ventilation immediately following elective extubation in more than three days of acute respiratory failure would decrease the need for re-intubation and hospital mortality compared to unassisted oxygen alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Committee of São Paulo Medical School on the 13th December 2000 (ref: 885/00)

Study design
Randomised, controlled, unblinded clinical study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute respiratory failure

Interventions
After the patients achieved elective extubation criteria they were randomised to receive non-invasive positive pressure ventilation immediately after extubation or receive oxygen mask alone.

The total duration for the treatment was 24 hours (use of noninvasive positive pressure ventilation after weaning). Reintubation criteria was reintubation required within a period of 48 hours after extubation. The need of reintubation was recorded as well as the length of ICU stay and hospital mortality.

Joint sponsor details:
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Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Decrement in the need of re-intubation, measured within 48 hours of extubation

Key secondary outcome(s))
1. Decrement of ICU length of stay
2. Decrement of hospital mortality

Completion date
15/01/1999

Eligibility

Key inclusion criteria
1. Patients aged 18 years or older, either sex
2. Need more than three days of mechanical ventilation administered by orotracheal intubation because of acute respiratory failure
3. Weaning from invasive mechanical ventilation using intensive care unit (ICU) weaning protocol
4. Absence of contraindications for the use of non-invasive ventilation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Less than 18 years of age
2. Pregnancy
3. Patients refusal to participate in the study

Date of first enrolment
15/01/1998

Date of final enrolment
15/01/1999

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Maranhão 654 apto 174
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Sponsor information

Organisation
University of São Paulo Medical School (Brazil)

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital de Base University of São José de Rio Preto (Brazil)

Funder Name
University of São Paulo Medical School (Brazil)

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	04/03/2013		Yes	No