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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Carmen Barbas

Contact details

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Additional identifiers

Protocol serial number N/A

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 reintubation 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

Brazil

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

Αll

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 São Paulo Brazil 01240-000

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