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

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

## Primary study design
Interventional

## Study design
Randomised, controlled, unblinded clinical study

## 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 |