

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/08/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/03/2013	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Decrement in the need of re-intubation, measured within 48 hours of extubation

Secondary outcome measures

1. Decrement of ICU length of stay
2. Decrement of hospital mortality

Overall study start date

15/01/1998

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40 patients

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

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Sponsor information**Organisation**

University of São Paulo Medical School (Brazil)

Sponsor details

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Sponsor type

University/education

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

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	04/03/2013		Yes	No