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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

Contact name
Prof Carmen Barbas

Contact details
Rua Maranhão 654 apto 174
São Paulo
Brazil
01240-000
+55 11 3826 1422
cbarbas@attglobal.net

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

Av. Brigadeiro Faria Lima 5544
Vila São Pedro
CEP: 15090-000
São José do Rio Preto
São Paulo
Brazil
Tel: +55 17 3201 5000
Fax: +55 17 3201 5000
Email: cbarbas@attglobal.net

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
Brazil
01240-000

Sponsor information

Organisation
University of São Paulo Medical School (Brazil)

Sponsor details
Av. Dr Eneas de Carvalho Aguiar 255
Sala 7079
São Paulo
Brazil
05403-900
+55 11 3826 1422
cbarbas@attglobal.net

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