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A new integrative weaning index of discontinuation from mechanical ventilation

Submission date 02/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/02/2009	**Overall study status** Completed	
Last Edited 29/03/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sergio Nemer

Contact details
Hospital de Clínicas de Niterói
Rua La Sale, 12
Centro, Niterói
Rio De Janeiro
Brazil
24020-090
snnemer@urbi.com.br

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A new integrative weaning index of discontinuation from mechanical ventilation: an observational study

Study objectives
A new integrative weaning index can predict the weaning outcome better than traditional indexes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committees of Hospital de Clínicas de Niterói approved in August 2004 (ref: USP/FM/SBD-033/07)

Study design
Observational cohort blinded (physician) trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mechanical ventilation weaning

Interventions
Patients were classified as weaned or not weaned according to the ability to sustain spontaneous breathing for more than 48 hours post-extubation. Continuous positive airway pressure (CPAP) of 5 cm H2O was provided to avoid reconnection to the ventilator where necessary. Patients that remained in non invasive ventilation (NIV) were considered as 'weaning in progress' and could not be classified as weaned or not weaned. Patients that presented with post-extubation respiratory failure received all care to avoid reintubation but were ventilated by NIV where necessary.

The indexes were measured by the respiratory physiotherapists before the spontaneous breathing trials (SBTs). The decision to return to mechanical ventilation was made by the

physician in charge (who was completely blind about the results of the indexes evaluated), based on the signs of poor tolerance.

The following measurements were taken for each weaning index:
1. Rapid shallow breathing index (f/Vt ratio)
2. Quasi-static compliance of the respiratory system (Cqst,rs)
3. Tidal volume
4. Respiratory rate
5. PaO2/FiO2 ratio
6. Volume minute
7. Airway occlusion pressure (P 0.1)
8. Integrative weaning index (Cqst,rs x arterial oxygen saturation / f/Vt ratio). This is a newly proposed index, used in some hospitals in Brazil.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Better accuracy in predicting weaning outcome

Secondary outcome measures
Adequate prognosis

Overall study start date
01/09/2004

Completion date
01/01/2008

Eligibility

Key inclusion criteria
Patients (both males and females) more than 24 hours in mechanical ventilation in weaning process.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
331

Key exclusion criteria
1. Patients younger than 18 years old
2. Neurological and neuromuscular diseases
3. Patients who have been tracheostomised

Date of first enrolment
01/09/2004

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Brazil

Study participating centre
Hospital de Clínicas de Niterói
Rio De Janeiro
Brazil
24020-090

Sponsor information

Organisation
Niterói Hospital (Hospital de Clínicas de Niterói) (Brazil)

Sponsor details
c/o Dr. Paulo Cesar Pereira de Souza
Rua La Sale, 12
Centro, Niterói
Rio de Janeiro
Brazil
24020-090
pcsouza@pobox.com

Sponsor type
Hospital/treatment centre

Website
http://www.hcniteroi.com.br

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Niterói Hospital (Hospital de Clínicas de Niterói) (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	01/07/2009		Yes	No