

A new integrative weaning index of discontinuation from mechanical ventilation

Submission date 02/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/03/2010	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

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

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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