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A pilot study of a new test to predict extubation failure

Submission date	Recruitment status	[_] Prospectively registered
07/08/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/09/2009	Respiratory	

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

Study objectives
We hypothesise that it is possible to further identify patients that are likely to require reintubation by subjecting patients to a burden in addition to that supposed by the spontaneous breathing test. The response to this burden could provide data that might be useful in deciding to extubate and help reduce extubation failure. This study aimed to determine the clinical and gasometric parameters registered during the dead space addition (DSA) test that are most reliable in predicting extubation failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethical Committee of Hospital del Mar, Municipal Institute for Health Care (Institut Municipal d'Assistència Sanitària) (CEIC-IMAS), approved on 12/05/2005.

Study design
Prospective non-randomised pilot study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Acute respiratory failure

Interventions
This is a non-randomised, single-arm, pilot study of the dead space addition (DSA) test which aims to detect increased risk of extubation failure.

DSA test procedure:
The DSA test consisted of adding a tube with an internal volume of 100 cc (measured by filling the tube with water) between the endotracheal tube and the T-piece with oxygen for 30 minutes. At the start of the test, BP, HR, RR, O2 saturation by pulDSA test.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Clinical signs of increased work of breathing (intercostal retractions, accessory muscle use, nasal flaring) were monitored during the DSA test.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2004

Completion date
31/10/2005

Eligibility

Key inclusion criteria
1. Both males and females, aged 18 or older
2. Improvement of the underlying cause of acute respiratory failure
3. Patients who fulfilled the criteria for extubation recommended by the Consensus Conference on Weaning after the 120-minute spontaneous breathing test: no signs of respiratory insufficiency (paradoxical breathing, abdominal breathing, agitation, excessive sweating, etc.), saturation of oxygen in arterial blood flow (SpO2) >90%, FiO2 <0.5, respiratory rate (RR) <35 /min, variation <20% in heart rate (HR) and blood pressure (BP)
4. Adequate gas exchange characterised by partial pressure of oxygen in arterial blood (PaO2) >60 mmHg, fraction of inspired oxygen (FiO2) <0.4 and positive end expiratory pressure (PEEP) <5 cm H2O
5. Glasgow Coma Scale >13
6. Body temperature <38°C
7. No need for vasoactive or sedative drugs

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
152

Key exclusion criteria
Tracheostomised patients

Date of first enrolment
01/11/2004

Date of final enrolment
31/10/2005

Locations

Countries of recruitment
Spain

Study participating centre
Hospital del Mar
Barcelona
Spain
08003

Sponsor information

Organisation
Hospital del Mar, Municipal Institute for Health Care (Institut Municipal d'Assistència Sanitària [IMAS]) (Spain)

Sponsor details
Passeig Maritim 25-29
Barcelona
Spain
08003

Sponsor type
Hospital/treatment centre

Website
http://www.imasbcn.com

ROR
https://ror.org/03a8gac78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital del Mar, Municipal Institute for Health Care (Institut Municipal d'Assistència Sanitària [IMAS]) (Spain)

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	01/11/2009		Yes	No