A pilot study of a new test to predict extubation failure

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

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)

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

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