

To assess the predictive value of the respiratory mode, automatic tube compensation, in the process of weaning from mechanical ventilation compared to another mode, namely pressure support ventilation

Submission date 15/09/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/03/2010	Condition category Surgery	<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

Protocol serial number
N/A

Study information

Scientific Title

Prediction of extubation outcome: a randomised, controlled trial with automatic tube compensation versus pressure support ventilation

Study objectives

The use of automatic tube compensation during a spontaneous breathing trial would have an advantage over pressure support in predicting successful extubation outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Helsinki Board of Rabin Medical Centre granted approval in April 2006 (ref: 2038).

Study design

Single-centre, interventional, randomised, controlled, prospective study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Weaning from mechanical ventilation

Interventions

Patients are blindly allocated to undergo a 1-hour spontaneous breathing trial with either automatic tube compensation (ATC) (patients breathed through the ventilatory circuit using flow-triggering and CPAP of 5 cm H₂O, FiO₂ less than 0.5 with the addition of ATC 100%, the ATC group) or pressure support ventilation (PSV) (patients breathed through the ventilatory circuit using flow-triggering and CPAP of 5 cm H₂O, FiO₂ less than 0.5 with the addition of 7 cm H₂O of pressure support, the PSV group). Patients tolerating the breathing trial underwent immediate extubation while patients not tolerating the trial were reconnected to the ventilator. Patients were followed up for 48 hours following extubation.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Tolerance of the spontaneous breathing trial: ability to maintain spontaneous breathing for greater than 48 hours after extubation.

Key secondary outcome(s)

Predictive value of the frequency to tidal volume ratio with ATC compared to the ratio without ATC.

Completion date

04/04/2008

Eligibility

Key inclusion criteria

1. Age range 18 - 76 years, either sex, in the intensive care unit
2. Have required mechanical ventilation for greater than 24 hours
3. Meet criteria for weaning:
 - 3.1. Improvement of the cause of respiratory failure
 - 3.2. Oxygen saturation greater than 92% with a fraction of inspired oxygen (FiO₂) of less than 50%
 - 3.3. Stable neurological status (Glasgow Coma Score [GCS] greater than 8)
 - 3.4. Require bronchial toilet less than twice in the 8 hours preceding the assessment
 - 3.5. No need for vasoactive drugs
 - 3.6. Receiving only minimal or no sedation
 - 3.7. Body temperature greater than 36°C and less than 38°C
 - 3.8. Level of pressure support less than 15 cm H₂O with a positive end-expiratory pressure (PEEP) level of 8 cm H₂O or less

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not comply with the above inclusion criteria.

Date of first enrolment

01/10/2006

Date of final enrolment

04/04/2008

Locations

Countries of recruitment

Israel

Study participating centre

General Intensive Care

Petah Tikva

Israel

49100

Sponsor information

Organisation

Rabin Medical Center (Israel)

ROR

<https://ror.org/01vjtf564>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Rabin Medical Center (Israel)

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	01/08/2009		Yes	No