ISRCTN16080446 https://doi.org/10.1186/ISRCTN16080446

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

Registration date
29/09/2008

Overall study status
Completed

Last Edited
12/03/2010

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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General Intensive Care
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/10/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

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)

Sponsor details
c/o Dr Jonathan Cohen
General Intensive Care
Petah Tikva
Israel
49100

Sponsor type
Hospital/treatment centre

Website
http://www.clalit.org.il/he-il

ROR
https://ror.org/01vjtf564

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Rabin Medical Center (Israel)

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	01/08/2009		Yes	No