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Daily evaluation and spontaneous respiratory test for shorter times in paediatric mechanical ventilation

Submission date	Recruitment status	[ ] Prospectively registered
31/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/04/2010	Respiratory	[ ] Record updated in last year

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
Daily evaluation and spontaneous respiratory test for shorter times in paediatric mechanical ventilation: a randomised controlled trial

Study objectives
In this study, we tested the hypothesis of the combination of a daily evaluation and application of a spontaneous respiratory test in children, being able to shorten the required mechanical ventilation time, compared to weaning based on our standard of care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Comitê de Ética em Pesquisa do Hospital Universitário da Universidade de São Paulo approved on the 19th January 2007 (ref: CEP-HU/USP:710/06 - SISNEP CAAE: 0819.0.015.000-06)
2. Comissão de Ética para Análise de Projetos de Pesquisa - CAPPesq da Diretoria Clinica do Hospital das Clínicas e da Faculdade de Medicina da Universidade de São Paulo approved on the 23rd November 2006 (ref: 992/06)

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Acute respiratory insufficiency

Interventions
All patients from the test group were submitted to a daily evaluation performed every morning by an intern not involved with the decision of extubation. This evaluation considered the following information: absence of new infiltrates according to the thoracic x-ray, fraction of inspired oxygen (FiO2) less than or equal to 50%, positive end expiratory pressure (PEEP) less than or equal to 8 cm H2O, inspiratory pressure (Pinsp) less than 25 cm H2O, presence of respiratory drive, absence of neuromuscular blocker in the last 24 hours, correction of hydrolytic

changes (calcium, phosphorus, magnesium, potassium), haemodynamic stability (use of sodium nitroprusside, dopamine and dobutamine up to 10 µg/Kg/min), no continuous sedation, and haemoglobin greater than or equal to 8 g/dL. This evaluation was performed daily until the patient was extubated.

Patients in the test group who fulfilled the daily evaluation were submitted to a spontaneous respiratory test with PEEP 5 cm H2O, pressure support of 10 cm H2O and FiO2 used before the test, for a period of two hours. The test was interrupted whenever patients presented any of the criteria characteristics of a faulty test: increase in respiratory frequency 20% above the initial value, signs of increased respiratory work (use of accessory muscles and paradoxical respiration), cardiac frequency 20% above the initial value, changes in consciousness level (restlessness or sleepiness), arterial pressure less than 5th percentile for patient's age, saturation less than 90%, gas carbonic arterial pressure (PaCO2) greater than 50 mmHg or an increase above 10 mmHg in 1 hour in chronic patients.

Right before the test and in the first hour of the test, two arterial blood gas analysis were collected. If the patient did not meet any of the criteria of a faulty test, extubation was performed. Otherwise, mechanical ventilation was re-established according to the previous parameters and the test repeated in 24 hours.

The respiratory test was not performed in the control group. Weaning was performed according to the routine procedure.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Duration of mechanical ventilation compared to weaning, measured at time of extubation

Secondary outcome measures
Measured 48 hours after extubation:
1. Faulty extubation rate
2. Need for post-extubation non-invasive mechanical ventilation

Overall study start date
01/07/2007

Completion date
01/07/2009

Eligibility

Key inclusion criteria
1. Children aged between 28 days and 15 years old, either sex
2. Admitted to the Hospital das Clínicas da Universidade de São Paulo - HCFMUSP and Hospital Universitário, Brazil, between July 2007 and July 2009
3. Underwent mechanical ventilation for a period over 24 hours

Participant type(s)
Patient

Age group
Child

Lower age limit
28 Days

Upper age limit
15 Years

Sex
Both

Target number of participants
294 children (139 = control group; 155 = test group)

Key exclusion criteria
1. Younger than 28 days
2. Intubation due to upper airway obstruction (UAO)
3. Lack of consent-form
4. Presence of hernia or diaphragmatic paralysis
5. Chronic use of mechanical ventilation
6. Congenital cyanogenic cardiopathy
7. Primary pulmonary hypertension
8. Neuromuscular disease
9. Tracheostomy

Patients were included in the study only once and only the first intubation of those patients requiring a re-intubation was considered in the analysis.

Date of first enrolment
01/07/2007

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
Brazil

Study participating centre
Rua do Chá, 21
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Sponsor information

Organisation
University of São Paulo (Brazil)

Sponsor details
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Sponsor type
University/education

Website
http://www.usp.br/internacional/home.php?idioma=en

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (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