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Helium-oxygen reduces the work of breathing during weaning from mechanical ventilation

Submission date 02/01/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2009	**Overall study status** Completed	
Last Edited 04/07/2011	**Condition category** 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
2005-003612-30

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REC ref: 05/Q0605/150

Study information

Scientific Title
A comparison of a helium-oxygen mixture (Heliox) with an oxygen air mixture in reducing the work of breathing during weaning from mechanical ventilation

Study objectives
There is evidence in patients with chronic obstructive pulmonary disease (COPD) that around the period of extubation helium-oxygen leads to a reduction in the work of breathing. In a small physiological study in patients without airways disease, breathing helium-oxygen during weaning decreased the work of breathing. If so, could there be a use for helium in the weaning of patients from mechanical ventilation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London & The City HA Local Research Ethics Committee 3, approved on 09/11/2005 (ref: 05/Q0605/150)

Study design
Prospective randomised controlled cross-over single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Work of breathing during weaning from mechanical ventilation

Interventions
This is a single-centre trial carried out at The Royal London Hospital.

Intervention: Helium inhaled at a concentration no less than 60%.

Patients received 2 hours of continuous positive airway pressure (CPAP) ventilation (positive end-expiratory pressure [PEEP] setting remained unchanged and pressure support set to zero) with helium-oxygen or air-oxygen via an eVent ventilator. This ventilator was calibrated for the helium oxygen mixture on an individual patient basis. Patients were returned to their pre-study ventilator settings for 2 hours, before being given the alternative gas mixture for 2 hours.

The level of CPAP support and FiO2 were unchanged for individual patients throughout the trial period.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Work of breathing measured by carbon dioxide production.

Measurements were taken continuously but presented before starting CPAP and helium then 1 hour later then at 2 hours, patient then returned to pre-CPAP ventilator settings for 2 hours then back on CPAP with alternate gas mixture with readings taken continuously but presented at 1 and 2 hours.

Secondary outcome measures
1. Respiratory rate
2. Pulse oximetry (SpO2)
3. Alveolar minute ventilation
4. Alveolar tidal volume
5. CO2 production
6. End tidal CO2
7. Alveolar dead space (Vd/Vt)

Above measurements were taken continuously but presented before starting CPAP and helium then 1 hour later then at 2 hours, patient then returned to pre-CPAP ventilator settings for 2 hours then back on CPAP with alternate gas mixture with readings taken continuously but presented at 1 and 2 hours.

Overall study start date
01/01/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. General adult intensive care unit (ICU) patients
2. Both males and females, aged between 18 and 80
3. The underlying cause of respiratory failure was improving
4. Pressure support ventilation of less than 10 cm H2O
5. No continuous intravenous sedation or inotropes
6. FiO2 less than or equal to 0.4 and requiring less than 10 cm H2O positive end expiratory pressure
7. Written informed consent from the patient or assent from their next of kin was obtained

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Failure to meet inclusion criteria
2. Inadequate analgesia
3. Pregnancy
4. Participation in other intervention trials in the past 30 days
5. Refusal of consent from the patient or assent from the next of kin

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Australia

United Kingdom

Study participating centre
Intensive Care Unit
Sydney
Australia
2031

Sponsor information

Organisation
Barts and The London NHS Trust (UK)

Sponsor details
c/o Gerry Leonard
Research and Development Department
Third Floor Rutland House
42-46 New Road
Whitechapel
London
England
United Kingdom
E1 2AX

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.org.uk

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
Barts and the London NHS Trust (UK)

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	26/08/2010		Yes	No