

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

Submission date 02/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/01/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/07/2011	Condition category Respiratory	<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

Clinical Trials Information System (CTIS)
2005-003612-30

Protocol serial number
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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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 (V_d/V_t)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

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**

United Kingdom

Australia

Study participating centre

Intensive Care Unit

Sydney

Australia

2031

Sponsor information**Organisation**

Barts and The London NHS Trust (UK)

ROR

<https://ror.org/00b31g692>

Funder(s)**Funder type**

Government

Funder Name

Barts and the London NHS Trust (UK)

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	26/08/2010		Yes	No