

A trial of Helium-Oxygen mixtures in the immediate Post Extubation period in adult intensive care, using novel Decision-Theoretic Statistical Methodology

Submission date 27/07/2006	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/09/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/05/2013	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Protocol serial number

Version 3.0 23/07/08; 05/Q0108/337

Study information

Scientific Title

Acronym

HOPE-DTSM

Study objectives

Do helium-oxygen gas mixtures reduce re-ventilation rate in adult Intensive Treatment Unit (ITU) patients at risk of extubation failure?

As of 24/03/2009 this record has been updated; all changes can be found in the relevant fields under the above update date. Please also note that the anticipated start and end date have also been updated; the initial information at the time of registration were:

Initial anticipated start date: 24/07/2006

Initial anticipated end date: 28/07/2008

Ethics approval required

Old ethics approval format

Ethics approval(s)

Reviewed by Cambridge Research Ethics Committee and given favourable opinion on January 18th 2006 (reference number: 05/Q0108/337)

Study design

Prospective, single centre, randomised controlled phase IV study employing a sequential statistical method.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post extubation respiratory failure or distress

Interventions

24/05/2013: Please note that this trial was stopped on 01/08/2009

Subjects are randomised to either helium-oxygen or air-oxygen.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Helium-oxygen gas mixture

Primary outcome(s)

Re-ventilation rate at 24 hours.

Key secondary outcome(s)

Partial pressure of oxygen in arterial blood (PaO₂)/fraction of inspired oxygen (FiO₂) ratios and partial pressure of carbon dioxide in arterial blood (PaCO₂) at four hourly intervals post-extubation.

Completion date

23/03/2011

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

Amended as of 24/03/2009:

1. Cuff leak less than 140 ml after 48 hours mechanical ventilation
2. Suction more often than 2-hourly in the 4 - 6 hours prior to extubation
3. Failure of earlier spontaneous breathing trial
4. Intubated for airway obstruction
5. Hypercapnia greater than 6 kPa (45 mmHg) on last gas prior to extubation
6. Glasgow Coma Score less than 8 (Verbal Score is 1)
7. Cough peak flow less than 70 l/min
8. Mechanical ventilation greater than 48 hours and Rapid Shallow Breathing Index greater than 57 and a positive fluid balance over the previous 24 hours
9. Mechanical ventilation greater than 48 hours and a positive fluid balance of greater than 1 litre over previous 24 hours

Initial information at time of registration:

1. Intubated for airway obstruction
2. Glasgow Coma Score of less than eight at extubation
3. Failing a rapid wean protocol
4. Significant bronchorrhoea
5. Cuff Leak of less than 140 ml
6. Cough peak flow less than 60 ml/min

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Amended as of 24/03/2009:

1. Recent or current diagnosis of pneumothorax, surgical emphysema, or fractured ribs
2. Patients in whom there is no intention to re-ventilate upon tracheal extubation i.e. terminal extubation
3. Patients who are extubated accidentally
4. Patients with a tracheostomy
5. Patients who have been admitted to intensive care electively following surgery
6. Patients who use non-invasive ventilation (NIV) at home
7. Patients in whom there is clinical doubt from the research team concerning the clinical decision to extubate the patient, where recourse to the critical care consultant on duty is not available
8. Next of kin refuse assent
9. Informed consent is refused by the patient or their legally appointed representative at any stage during or after data collection

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2. Patients in whom there is no intention to re-ventilate upon tracheal extubation i.e. terminal extubation
3. Patients who are extubated accidentally
4. Patients with a tracheostomy
5. Patients who have been admitted to Intensive Care following elective surgery
6. Next of kin refuse assent
7. Informed consent is refused by the patient or their legally appointed representative at any stage during or after data collection

Date of first enrolment

23/03/2009

Date of final enrolment

23/03/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

John Farman Intensive Care Unit

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Industry

Funder Name

BOC Medical (UK)

Funder Name

Cambridge University Hospitals NHS Foundation Trust (UK) - Division of Anaesthesia, Addenbrookes Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration