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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	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 22/09/2006	**Overall study status** Stopped	
Last Edited 24/05/2013	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Vilas Navapurkar

Contact details
John Farman Intensive Care Unit
Box 17
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 217433
vilas@vilas.orangehome.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Re-ventilation rate at 24 hours.

Secondary outcome measures
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.

Overall study start date
23/03/2009

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

Age group
Adult

Sex
Both

Target number of participants
Over 100

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

Initial information at time of registration:
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 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
England

United Kingdom

Study participating centre
John Farman Intensive Care Unit
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Box 277, Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

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

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