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A randomised controlled trial evaluating the effectiveness of heliox in post-extubation stridor

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/03/2016	Surgery	[ ] 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

N0241121241

Study information

Scientific Title
A randomised controlled trial evaluating the effectiveness of heliox in post-extubation stridor

Study objectives
Does heliox have a role to play in the immediate management of post-extubation stridor, in reducing adrenaline requirement and need for re-intubation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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
Intubation

Interventions
Patients will be extubated initially into 30% FiO2, and their SpO2 recorded when stable for scoring purposes. Higher or lower FiO2 can then be given if needed. Patients will be entered into the study if they have any stridor at all (ie modified Syracuse score 1 or more) between 5 min and 24 h post extubation. This will be assessed by a doctor who is prepared to immediately randomise, and to start heliox if indicated. If stridor develops earlier than 5 min it should be observed if still present at 5 min then proceed with randomisation. As soon as a patient becomes eligible, he/she will be randomised by coin toss: HEads for HEliox , tails to simply continue on required FiO2. Patients randomised to heliox will commence this immediately.

The modified Syracuse score (DEVELOPED FOR THIS STUDY BUT BASED ON A VALIDATED SCORE - see below for details) will be scored:
1. At 5 minutes post-extubation;

2. At the moment that stridor is first recognised;
3. One minute after randomisation;
4. Every thirty minutes after randomisation, until the trial ends; and
5. At the end of any dose of nebulised adrenaline

Any patient with a modified Syracuse score of 3 or more at points 3, 4 or 5 will receive nebulised adrenaline 1:1000 0.5ml/kg (maximum single dose 5ml). If the score remains 3 or more at the completion of a nebuliser, the dose will be immediately repeated; if not, no further dose will be given until the next score (30 minutes after the last, pre-nebuliser score). A modified Syracuse score of 3 or more persisting after three continuous adrenaline nebulisers will be an indication for re-intubation.

Once started, heliox may be stopped if the modified Syracuse score is 0 on three successive occasions (i.e. for one hour). A further two scores should be obtained thereafter: if stridor returns within one hour off heliox, it may be recommenced.

A patient's involvement in the trial will be ended on any of the following:
1. the parent demands withdrawal from the study
2. the clinician feels that the study is compromising patient care
3. the patient is re-intubated
4. the patient is free of stridor for one hour, not being on heliox.

If a patient exits the trial and subsequently develops stridor again (within 24 hours of extubation), he/she may be re-entered and re-randomised. Thus one patient may enter the trial more than once, potentially in different treatment arms, if he/she has more than one episode of stridor separated by at least one hour.

Pre-extubation dexamethasone is neither encouraged nor discouraged by this trial, but should be recorded in either event. The avoidance of steroids would probably increase the numbers of patients eligible for the study; however, it would not be ethical to deny the patient this treatment if the clinician felt it was clinically indicated.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. Stridor scores analysed by Student's t-test
2. Adrenaline use (directly linked to stridor scores) analysed by Student's t-test
3. Re-intubation rates analysed by Chi-squared test

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/03/2003

Completion date
31/08/2003

Eligibility

Key inclusion criteria
All children intubated are eligible for the trial. Parents will be approached and consented at the appropriate time (prior to planned extubation).

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
10 (minimum)

Key exclusion criteria
Patients with undrained pneumothoraces or intracranial air will be excluded.

Date of first enrolment
27/03/2003

Date of final enrolment
31/08/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
PICU
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Mary's 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