Bronchiolitis randomised controlled trial (RCT): **Emergency Assisted Therapy with Heliox - an Evaluation**

Submission date	Recruitment status	[X] Prospectively registe		
21/09/2005	No longer recruiting	[] Protocol		
Registration date	Overall study status	[] Statistical analysis pl		
29/09/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant		
22/05/2013	Respiratory			

Plain English summary of protocol

Not provided at time of registration

Study website http://www.breathe-heliox.com

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

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t data

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers HP002A

Study information

Scientific Title

Acronym BREATHE

Study objectives

Helium-oxygen gas mixtures reduce the total duration of treatment needed in the management of bronchiolitis

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) Not specified

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied Bronchiolitis

Interventions

1. Heliox-21 +/- additional oxygen

2. Medical air +/- additional oxygen

Intervention Type

Drug

Phase Not Specified

Drug/device/biological/vaccine name(s)

Helium-oxygen gas

Primary outcome measure Total length of treatment needed

Secondary outcome measures

- 1. Proportion of cases needing continuous positive airway pressure (nCPAP)
- 2. Duration of nCPAP needed
- 3. Changes in clinical assessment parameters and measurements

Overall study start date

03/10/2005

Completion date 31/08/2007

Eligibility

Key inclusion criteria

- 1. Chronological age = 1 year or less
- 2. Bronchiolitis likely as a diagnosis
- 3. Requiring admission for treatment of respiratory distress or hypoxia (i.e. SpO2 <93%)

Participant type(s) Patient

Age group

Child

Upper age limit 1 Years

Sex Both

Target number of participants 298

Key exclusion criteria

- 1. Any condition requiring immediate intubation (including apnoea or bradycardia)
- 2. Unable to maintain SpO2 >92% despite 15 l/min oxygen
- 3. Legal incapacity of parent/guardian to give consent
- 4. Participating in another drug trial in the past 4 weeks
- 5. Inappropriate for child to enter study, in clinician's opinion
- 6. Child has a tracheostomy

7. Readmitted (with a diagnosis of bronchiolitis) within 24 hours of exiting from the BREATHE study

- 8. If any of the following drugs were given prior to entry/enrolment into the BREATHE study:
- a. Salbutamol or ipratropium/atrovent (less than 1 hour prior to entry into BREATHE)
- b. Adrenaline (less than 1 hour prior to entry into BREATHE)
- c. Systemic steroids (less than 4 hours prior to entry into BREATHE)

Date of first enrolment

03/10/2005

Date of final enrolment

31/08/2007

Locations

Countries of recruitment England

United Kingdom

Study participating centre Department of Paediatrics London United Kingdom W2 1PG

Sponsor information

Organisation Imperial College London (UK)

Sponsor details

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Sponsor type University/education

Website http://www.imperial.ac.uk

ROR https://ror.org/041kmwe10

Funder(s)

Funder type Industry

Funder Name BOC Medical

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	01/04/2013		Yes	No