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

Submission date 21/09/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2005	**Overall study status** Completed	
Last Edited 22/05/2013	**Condition category** 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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Additional identifiers

EudraCT/CTIS number

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
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W2 1PG

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Faculty of Medicine
Level 2, Faculty Building
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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