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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Total length of treatment needed

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

1 years

Sex

All

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

United Kingdom

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

Sponsor information

Organisation

Imperial College London (UK)

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type

Industry

Funder Name

BOC Medical

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes