ISRCTN18238432 https://doi.org/10.1186/ISRCTN18238432

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
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/05/2013	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Parviz Habibi

Contact details
Department of Paediatrics
Room 250
Wright Fleming Institute
St Mary's Campus
Imperial College London
Norfolk Place
London
United Kingdom
W2 1PG
+44 (0)20 7594 3990
p.habibi@imperial.ac.uk

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

England

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes