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Trial of nasal CPAP (Continuous Positive Airways Pressure) in infants with bronchiolitis

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2022	Respiratory	

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
N0205134443

Study information

Scientific Title
Trial of nasal CPAP (Continuous Positive Airways Pressure) in infants with bronchiolitis

Study objectives
This study aims to identify which treatment modality (CPAP [Continuous Positive Airways Pressure] or traditional supportive management) is more successful in infants with 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)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
A pilot study. A randomised cross-over design will be used. Infants who have reached the inclusion criteria will be randomised to either 12 hours of CPAP or 12 hours of traditional supportive management. They will then cross over into the other arm, to act as their own controls, and receive further hours of the opposite treatment. After 24 hours their clinical management will be as of the team looking after the child.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Change in partial pressure of Carbon dioxide (pCO2)
2. Change in Fraction of inspired Oxygen (FiO2)
3. Change in heart rate
4. Change in respiratory rate

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2001

Completion date
01/06/2005

Eligibility

Key inclusion criteria
Children less than one year of age with a clinical diagnosis of bronchiolitis.

Participant type(s)
Patient

Age group
Child

Upper age limit
1 Years

Sex
Not Specified

Target number of participants
31

Total final enrolment
31

Key exclusion criteria
No exclusion criteria

Date of first enrolment
01/11/2001

Date of final enrolment
01/06/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Paediatric department
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Barts and The London 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
Not provided at time of registration

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		01/01/2008		Yes	No