

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S Carr

Contact details
Paediatric department
2nd Floor, Fielden House
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB
+44 (0)20 7377 7462
siobhan.carr@bartsandthelondon.nhs.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

1 years

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Paediatric department

London

United Kingdom

E1 1BB

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Barts and The London NHS Trust (UK)

Results and Publications

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