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A pilot randomised controlled study of oxygen delivery via Vapotherm® in infants with severe acute bronchiolitis

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 08/05/2013	**Condition category** 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

N0264191693

Study information

Scientific Title

Study objectives
We wish to study the safety and efficacy of the Vapotherm oxygen delivery device in infants with severe acute bronchiolitis in an initial pilot trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised open pilot study

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: Severe acute bronchiolitis

Interventions
Randomised open pilot study of oxygen delivery via Vapotherm compared with conventional therapy (optimum oxygen delivery via a headbox and appropriate intravenous fluids. Parents have up to 6 hours to decide whether to take part.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vapotherm®

Primary outcome measure
Oxygen saturation (SpO2) 8 hours post randomisation to either Vapotherm or continuing conventional therapy.

Secondary outcome measures
1. SpO2, heart rate, respiratory rate, FiO2 (oxygen concentration), blood pressure and combined bronchiolitis
2. Severity score at 4 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours after point of randomisation
3. Length of stay in hospital; length of time receiving oxygen therapy after randomisation; length of time before enteral feeds re-started after randomisation
4. Proportion of infants in each group that require further respiratory support, with either CPAP or intubation and mechanical ventilation

Overall study start date
15/01/2007

Completion date
15/05/2007

Eligibility

Key inclusion criteria
Subjects will be infants less than 12 months of age admitted to hospital with a clinical diagnosis of
1. Bronchiolitis (clinical picture of cough, tachypnoea, chest retraction and crackles on auscultation) and
2. Features of severe disease:
2.1 Head–box oxygen requirement greater than 50% to maintain SpO2 at least 92%
2.2 Feeds have been discontinued, and intravenous fluid started
2.3 Moderate to severe tachypnoea and increased work of breathing
2.4 Triggering of the Paediatric Early Warning Tool

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
32 infants

Key exclusion criteria
1. Congenital cyanotic heart disease
2. Repeated severe apnoeas
3. Requirement for resuscitation with bag-mask ventilation
4. Severe hypercapnia (increased carbon dioxide) with acidosis on blood gas analysis of pH less

than 7.2
5. Parental refusal or inability to give consent

Date of first enrolment
15/01/2007

Date of final enrolment
15/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
C/O Research and Effectiveness Department
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
United Bristol Healthcare NHS Trust

Funder Name
NHS R&D Support Funding

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	01/02/2012		Yes	No