

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/09/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>28/09/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>08/05/2013       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data                                              |

**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 (SpO<sub>2</sub>) 8 hours post randomisation to either Vapotherm or continuing conventional therapy.

**Secondary outcome measures**

1. SpO<sub>2</sub>, heart rate, respiratory rate, FiO<sub>2</sub> (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 SpO<sub>2</sub> 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

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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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/02/2012   |            | Yes            | No              |