ISRCTN28405428 https://doi.org/10.1186/ISRCTN28405428

# Bronchiolitis of Infancy Discharge Study

**Submission date**
04/03/2011

**Recruitment status**
No longer recruiting

**Registration date**
15/03/2011

**Overall study status**
Completed

**Last Edited**
21/09/2015

**Condition category**
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Bronchiolitis is a common viral lung infection that affects babies and young children under two years old. The majority of infants admitted to hospital with bronchiolitis require supplemental oxygen, but two recent guidelines differ in what experts considered to be the correct blood oxygen level (oxygen saturation) to stop giving supplemental oxygen; one recommended 90% and the other 94%. We aimed to demonstrate that supplemental oxygen does not make any difference to symptoms if stopped at stable 90% oxygen saturation as opposed to the current 94%.

Who can participate?
Infants between 6 weeks and 12 months of age, admitted to hospital with bronchiolitis.

What does the study involve?
Participating infants were randomly allocated to either a standard or a modified monitor to measure their oxygen saturation levels during their hospital stay. Modified monitors displayed a different oxygen saturation level to that measured (within a small range). Clinical outcomes were monitored and parents were followed up to collect information on healthcare and societal costs and parental anxiety levels. Parents completed questionnaires at the start of the study and then by phone after 7 and 14 days and after 6 months to ask about their child's health and their experience. After 28 days we again met the infants enrolled during the first year of the study to check their oxygen levels and ask about the child's health.

What are the possible benefits and risks of participating?
Infants in the study had different types of oxygen saturation monitor but no extra tests. Our study investigated whether the use of supplemental oxygen reduces the length of illness or use of healthcare resources once an infant attains satisfactory oral feeding and a stable arterial oxygen saturation of 90% in room air (as opposed to typical 94% in room air). This difference could represent 22 hours longer in hospital.

Where is the study run from?
Five children's hospitals in Scotland (Aberdeen, Dundee, Edinburgh, Glasgow and Kilmarnock) and three in South West England (Bristol, Exeter and Truro) took part in the study, which was coordinated by the Edinburgh Clinical Trials Unit.

When is the study starting and how long is it expected to run for?
Infants were recruited over two winters (October 2011 – March 2012 and October 2012 – March 2013) to coincide with the busy bronchiolitis season.

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK).

Who is the main contact?
Dr Steve Cunningham

# Contact information

### Type(s)
Scientific


### Contact name
Dr Steve Cunningham

### ORCID ID
http://orcid.org/0000-0001-7342-251X

### Contact details
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
HTA 09/91/16, BIDS_1.0

# Study information

### Scientific Title
Bronchiolitis of Infancy Discharge Study: a multi-centre, parallel-group, double blind, randomised controlled, equivalence study

### Acronym
BIDS

### Study objectives

In infants admitted to hospital with acute viral bronchiolitis, oxygen supplementation does not alter symptom duration or further healthcare use once infants have attained a stable oxygen saturation ≥ 90% in room air.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/099116
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/54771/PRO-09-91-16.pdf

On 16/06/2015 the overall trial end date was changed from 29/03/2013 to 30/10/2013.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South East Scotland Research Ethics Committee 03, 07/06/2011

## Study design
Multi-centre parallel-group double-blind randomised controlled equivalence study

## Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Acute admission with bronchiolitis in infants ≥ 6 weeks and ≤ 12 months of age

## Interventions
To test whether acceptance of lower oxygen saturation limits influences recovery from acute bronchiolitis, randomisation will be to a standard or modified pulse oximeter.

Standard oximeters will measure and display arterial oxygen saturation (SpO2) as usual care. Modified oximeters will measure arterial oxygen saturation as usual, but manufacturer altered internal algorithms will alter the display to nonstandard; a measured range of SpO2 85-90% will display as a range of SpO2 85-94%.

## Intervention Type
Other

## Phase

Not Applicable

### Primary outcome measure
Time from randomisation to resolution of cough. For this outcome measure, we will be testing for equivalence between the two arms of the trial

### Secondary outcome measures
For these outcome measures, we will be testing for difference between the two arms of the trial

1. Time from randomisation to
1.1. Fit for discharge
1.2. Actual discharge for all infants admitted with acute viral bronchiolitis (ward based data)
2. Proportion of infants with healthcare re-attendance (primary care, emergency department, readmission) (parental phone calls)
3. Change in parental anxiety score between admission and 28 days post admission (home visit questionnaire)
4. Time to return to work/usual activities for parent(s) post admission (parental phone call)
5. Time to return to nursery for infant post admission (parental phone call)
6. Family costs incurred related to time to return to work/nursery (demographic questionnaire and parental phone call)
7. Societal costs for parental return to work (demographic questionnaire and parental phone call)
8. Healthcare costs related to discharge time and subsequent healthcare utilisation (ward based data and parental phone calls)

For these outcome measures, we will be testing for equivalence between the two arms of the trial

1. Time from randomisation to re-established feeding (approximately 75% normal) (nursing observation). Accept equivalence of 20% variance, consider as 4 hours based on previous data
2. Time from randomisation to parental perspective of back to normal (feeding, sleeping and asymptomatic) (parental phone call). Accept equivalence of 2 days, based on responses of clinicians to cough resolution times
3. Awake oxygen saturation at 28 days post randomisation (home visit). Accept equivalence of 1.0% SpO2, based on studies demonstrating healthy infant oxygen saturation

### Overall study start date
03/10/2011

### Completion date
30/10/2013

## Eligibility

### Key inclusion criteria
Infants ≥ 6 weeks and ≤ 12 months of age, admitted to hospital with a clinical diagnosis of bronchiolitis made by a medically qualified practitioner in a emergency department (ED)/AAA

### Participant type(s)
Patient

### Age group

Neonate

### Sex
Both

### Target number of participants
600

### Key exclusion criteria
1. Preterm (< 37 weeks gestation) who received home oxygen therapy in the past 4 weeks
2. Haemodynamically significant congenital heart disease
3. Cystic fibrosis or Interstitial lung disease
4. Documented immune function defect

### Date of first enrolment
03/10/2011

### Date of final enrolment
29/03/2013

## Locations

### Countries of recruitment
England

Scotland

United Kingdom

### Study participating centre
**Royal Hospital for Sick Children**
Edinburgh
United Kingdom
EH9 1LF

### Study participating centre
**Royal Aberdeen Children's Hospital**
Westburn Road
Fosterhill
Aberdeen
United Kingdom
AB25 2ZG

### Study participating centre

**Ninewells Hospital and Medical School**
Dundee
United Kingdom
DD1 9SY

**Study participating centre**
**Royal Hospital for Sick Children**
Dalnair Street
Glasgow
United Kingdom
G3 8SJ

**Study participating centre**
**Crosshouse Hospital**
Kilmarnock Road
Crosshouse
United Kingdom
KA2 0BE

**Study participating centre**
**Bristol Children's Hospital**
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

**Study participating centre**
**Royal Cornwall Hospital**
Treliske
Truro
United Kingdom
TR1 3LJ

**Study participating centre**
**The Royal Devon and Exeter Hospital**
Barrack Road
Wonford
United Kingdom
EX2 5DW

# Sponsor information

### Organisation
The University of Edinburgh and NHS Lothian (UK)

### Sponsor details
Academic and Clinical Central Office for Research and Development
Research & Development Management Suite
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ

### Sponsor type
University/education

### ROR
https://ror.org/03q82t418

# Funder(s)

### Funder type
Government

### Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) (HTA 09/91/16)

# Results and Publications

### Publication and dissemination plan
1. Primary clinical outcome has been submitted for publication but is still under review.
2. The NIHR HTA clinical study report will be published immediately after the peer-review journal publication.
3. A further two papers are in preparation with plans to submit to peer review journals by December 2015.

### Intention to publish date
01/07/2015

### Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/09/2015 | | Yes | No |
| Results article | results | 12/09/2015 | | Yes | No |