

Bronchiolitis of Infancy Discharge Study

Submission date 04/03/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/09/2015	Condition category Respiratory	<input type="checkbox"/> 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

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Additional identifiers

Protocol serial number
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 $\geq 90\%$ 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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**

United Kingdom

England

Scotland

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)

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

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