ISRCTN52937119 https://doi.org/10.1186/ISRCTN52937119

Evaluating the clinical and cost effectiveness of breathing support treatment types in infants under 12 months of age with acute bronchiolitis

Submission date
14/08/2023

Recruitment status
Recruiting

Registration date
04/09/2023

Overall study status
Ongoing

Last Edited
04/09/2023

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Nearly 30,000 infants under one are admitted to hospitals in England each year with bronchiolitis, a common viral chest infection. Half of them need oxygen treatment through 'nasal cannula' (thin tubes inserted into the nostrils). Most infants respond to nasal cannula oxygen alone, but some need additional breathing support. In these infants, different treatments such as 'humidified' (moist) standard oxygen (HSO), high-flow nasal cannula (HFNC) and 'CPAP' (pressurised oxygen delivered through the nose) are used. However, it is not clear which of these treatments should be started and when.

HFNC, which provides warm, humidified oxygen at high flow rates, has become a popular breathing support treatment in bronchiolitis, and has mostly replaced the use of HSO in moderately ill infants. HFNC is also used in many hospitals as an alternative to CPAP in severe bronchiolitis. There is little research to show whether HFNC is better than HSO or CPAP. Since HFNC requires specialist equipment, it is more expensive and requires expert nursing resources. There is also concern HFNC may prolong hospital stay.

Who can participate?
Infants aged less than 12 months with moderate or severe bronchiolitis.

What does the study involve?
For this research, we will conduct two clinical trials at the same time to determine the effectiveness of HFNC. Infants with moderate bronchiolitis will be randomly allocated to start either HFNC or HSO, and infants with severe bronchiolitis HFNC or CPAP. All other treatment decisions will be left to the clinical team.

We will recruit 1508 infants (924 moderate and 584 severe bronchiolitis) over a 30-month period from children's emergency departments and wards in 50 NHS hospitals. We will compare the treatments by measuring how quickly infants are discharged from hospital. We will also study other important outcomes such as patient comfort and parent/carer satisfaction. Our findings will inform national and international guidelines on the care of infants with bronchiolitis.

What are the possible benefits and risks of participating?
We do not believe that there will be any direct benefit nor disadvantage to patients taking part in this study. The first treatment option that patients would have received if they were not part of the study would still have been humidified oxygen, CPAP or high-flow, but the decision would have been made by the doctor and care team instead of the study. These three treatments are being used widely across the NHS already and have all been shown to be safe. However, the information gained from patients' participation in this study may help to improve the diagnosis and treatment of unwell children in the future. There is no monetary benefit as participants will not be paid to participate.

While the study interventions are all standard of care treatment options, the study team have considered and sought to mitigate risks that occur solely as a result of the study such as in the use of patients' data for this research. All data will be collected, processed and stored by the study team appropriately and correctly to the highest standards of confidentiality and security. The study will comply with all relevant regulations regarding use of data and data protection. Only de-identified or pseudonymised information would be shared between study partners. All our study teams will have received training in BACHb processes and procedures and would work in accordance with the principles of Good Clinical Practice (GCP).

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
April 2023 to September 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Richard Cleaver, r.cleaver@imperial.ac.uk

Study website
https://www.bachbtrial.org.uk

Contact information

Type(s)
Public

Contact name
Mr Richard Cleaver

Contact details
Imperial College London
Room 5.03
5th Floor, Medical School Building
St Mary's Campus
Norfolk Place
London
United Kingdom
W2 1PG

+44 7999 044627
r.cleaver@imperial.ac.uk

Type(s)
Principal Investigator

Contact name
Dr Padmanabhan Ramnarayan

ORCID ID
http://orcid.org/0000-0003-0784-8154

Contact details
Imperial College London
Room 508, 5th Floor, Medical School Building
St Mary's Campus, Norfolk Place
London
United Kingdom
W2 1PG
-
p.ramnarayan@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327621

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57649, NIHR152262, IRAS 327621, 22HH7629

Study information

Scientific Title
Breathing Assistance in CHildren with bronchiolitis (BACHb): a group-sequential two-stratum multicentre open-label randomised clinical trial of respiratory support in infants with acute bronchiolitis

Acronym
BACHb

Study objectives

1. In hospitalised infants with bronchiolitis not responding to low-flow nasal cannula oxygen (moderate bronchiolitis), use of HFNC is superior to HSO in reducing time to hospital discharge.
2. In hospitalised infants with bronchiolitis and severe respiratory distress (severe bronchiolitis), use of HFNC is superior to CPAP in reducing time to hospital discharge.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/08/2023, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 104 8184; southyorks.rec@hra.nhs.uk), ref: 23/YH/0166

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Bronchiolitis

Interventions
BACHb is a randomised clinical trial – this means children eligible for the study, depending on whether they have moderate or severe bronchiolitis, will be randomly put into one of two groups:
Moderate bronchiolitis: Group 1 will start Humidified Standard Oxygen (HSO), and Group 2 will start High Flow Nasal Cannula (HFNC)
Severe bronchiolitis: Group 1 will start Continuous Positive Airway Pressure (CPAP), and Group 2 will start HFNC

To make sure it is fair, children are put into the groups at random by a computer programme so they have an equal chance of being in Group 1 or Group 2. Randomisation will be performed soon after confirming eligibility and as close as possible to the anticipated start of the randomised treatment. Randomisation will be performed using a web-based system. If the initial breathing support treatment is not working, the trial allows doctors and nurses to change to a different treatment.

The procedures/data collection schedule for patients enrolled into the trial is:

BASELINE VISIT
Clinical/baseline data will be collected along with details of types of breathing support received (including weaning, switches and escalations from Humidified Standard Oxygen (HSO), High Flow Nasal Cannula (HFNC), Continuous Positive Airway Pressure (CPAP)) and patient comfort (FLACC score).

AT THE TIME OF CONSENT
Patient/parent details will be collected in addition to Patient comfort (parent/carer reported).

DURING BREATHING SUPPORT
Types of breathing support received will be documented as well as patient comfort (FLACC score) and safety monitoring data throughout the patients participation in the trial.

END OF HOSPITAL STAY
Data will be collected on the details of the discharge aswell as and newly identified safety monitoring data.

FOLLOW UP AT 30 DAYS AND 90 DAYS
IQI and Health services/resource use questionnaires will be given to parents/guardians to complete and both of these time points.
Once a child has been randomised the hospital research team will collect pseudonymised items of information for BACHb about participants treatments and their progress during their hospital stay until the end of the study/the child's discharge from hospital. If parents/guardians agree they will be contacted at one and three months after their child has left hospital with 2 short questionnaires to find out how the child is doing. These can be e-mailed (to an NHS e-mail account) or posted (with a pre-paid return envelope) to the parent/guardian or they will be e-mailed a link to the study OpenClinica database to complete the questionnaires directly on the database. These will be the final research data collection points and 3 months after discharge from hospital will mark the end of involvement in this study.

Intervention Type
Procedure/Surgery

Primary outcome measure
Time from randomisation to hospital discharge measured using patient records

Secondary outcome measures
Measured using patient records to end of hospital stay (unless noted otherwise)
1. Proportion of infants experiencing treatment failure
2. Mortality at hospital discharge, day 30 and day 90
3. Proportion of infants requiring intubation and ventilation
4. Proportion of infants requiring admission to an intensive care unit
5. Proportion of infants requiring sedation
6. Duration of oxygen therapy, defined as the time to being free from supplemental oxygen for >4 hours
7. Time to adequate (75%) oral feeding
8. Time ready for hospital discharge, defined as the time from randomisation to latest of time to being free of supplemental oxygen or adequate oral feeding.
9. Patient comfort, assessed by the caregiver using the FLACC scale.

10. Patient comfort, assessed by the parent/guardian using a visual analogue scale
11. Proportion of infants requiring hospital readmission within 30 days
12. Health status at 30 and 90 days
13. Cost-effectiveness expressed in terms of incremental cost per quality-adjusted life year (QALY) gained

Overall study start date
01/04/2023

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Hospitalised infant aged < 12 months with a clinical diagnosis of acute bronchiolitis AND
2. Clinically assessed at least twice 15 minutes apart to have EITHER:
2.1. Severe respiratory distress (respiratory rate > 70/min, or grunting, or marked chest recession) and/or recurrent short apnoeas (> 3 per hour, each apnoea lasting < 10 sec) [SEVERE BRONCHIOLITIS stratum], OR
2.2. Lack of response to LFNC oxygen up to 2 L/min, as indicated by persistent hypoxia (SpO2 < 90%, or < 92% if age < 6 weeks or if underlying health problems present) and/or moderate respiratory distress (respiratory rate 55-70/min and moderate chest recession) [MODERATE BRONCHIOLITIS stratum].

Participant type(s)
Patient

Age group
Child

Upper age limit
12 Months

Sex
Both

Target number of participants
Planned Sample Size: 1,508; UK Sample Size: 1,508

Key exclusion criteria
1. Clinical decision that patient needs immediate intubation and ventilation for life-threatening hypoxia, shock or decreased conscious level.
2. Prolonged apnoeas (> 10 seconds needing stimulation).
3. Ongoing active air leak (pneumothorax, pneumomediastinum).
4. Received HSO, HFNC or CPAP for over 2 hours in the previous 24 hours.
5. On home ventilation prior to hospital admission.
6. Tracheostomy in place.
7. Choanal atresia/stenosis, midfacial anomalies or recent craniofacial surgery.
8. Previously recruited to the BACHb trial.

Date of first enrolment
01/09/2023

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre

University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Barking, Havering and Redbridge University Hospitals NHS Trust
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre

Walsall Healthcare NHS Trust
Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
North West Anglia NHS Foundation Trust
Peterborough City Hospital
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Dartford and Gravesham NHS Trust
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA

Study participating centre

London North West University Healthcare NHS Trust
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Salisbury NHS Foundation Trust
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre

Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Sponsor information

Organisation
Imperial College London

Sponsor details
Faculty Building
London
England
United Kingdom
SW7 2AZ
+44 207 594 9459
rgit@imperial.ac.uk

Sponsor type
University/education

Website
http://www.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/09/2027

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date