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Treating breathing difficulties in young children diagnosed with bronchiolitis

Submission date
18/09/2017

Recruitment status
No longer recruiting

Registration date
18/12/2017

Overall study status
Completed

Last Edited
11/03/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Bronchiolitis is a very common respiratory condition that generally affects young babies and children up to two years of age. Symptoms include breathing difficulties, cough and poor feeding. Most children can be looked after at home but a small number of young children need to come into hospital for oxygen to treat their breathing difficulties. For a small number of children admitted to hospital their breathing difficulties will worsen and they will need to be admitted to intensive care. To try and prevent a child from worsening, health care professionals will provide treatments that will open up the small airways in their lungs. This is done by giving oxygen through the nose at either high pressures or at high flow rates. Importantly, it is not known which one of these two oxygen treatments is best or if they work. Due to the lack of research evidence, how and when these treatments are used in the UK varies a lot. The long term aim of this research is to find out the best way of treating breathing difficulties in children with bronchiolitis. Before this can be done it is necessary to know if this research is possible. This study includes a national survey of healthcare professionals, and will collect information on the number of children admitted to hospital. A series of focus group workshops and an online survey for healthcare professionals and parents are run to discuss opinions on treatment and to find out which outcomes of treatment are most important. The aim of this study is to be able to decide if a large trial comparing different ways of treating children with bronchiolitis in hospital with breathing difficulties is possible and warranted.

Who can participate?
Parents/carers of hospitalised children aged 0-24 months who are diagnosed with bronchiolitis and health care professionals with at least six months of experiencing managing children diagnosed with bronchiolitis.

What does the study involve?
Participants are invited to participate in focus groups, a Delphi survey or a telephone interview (parents/carers only). The workshop involves three focus groups to cover the identifying and prioritising outcomes, trial design and consent. The parent telephone interviews concentration on identifying and prioritising outcomes. The Delphi survey ask participants to rate each outcome (determined by literature review, workshops and telephone interviews) for importance. A national survey is sent to paediatricians at NHS hospital asking about bronchiolitis

management. Participants in the workshops, interview and survey are invited to attend an end of study event where the study data is presented and they agree on the future trial design and core outcome set.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participation.

Where is the study run from?
This study is being run by Alder Hey NHS Foundation Trust (UK) and takes place in hospitals in the UK.

When is the study starting and how long is it expected to run for?
February 2016 to September 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Clare van Miert

Contact information

Type(s)
Scientific

Contact name
Mrs Clare van Miert

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Contact details
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L12 2AP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20745

Study information

Scientific Title
Non-invasive ventilation for the management of children with bronchiolitis: a feasibility study

Acronym
NOVEMBR

Study objectives
The long term aim of the study is to find out how to best provide respiratory support to children with bronchiolitis when they are admitted to hospital.

Primary aims of the study are to:
1. To develop a core outcome set (COS) for use in future clinical trials in bronchiolitis
2. To explore issues critical to the design of a randomised controlled trial of non-invasive ventilation in infants with bronchiolitis
3. To comprehensively assess current UK practice as regards bronchiolitis management, potential trial capability and acceptability

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Authority, Yorkshire & The Humber – South Yorkshire Research Ethics Committee, 15/01/2016, ref: 16/YH/0012

Study design
Observational; Design type: Qualitative

Primary study design
Observational

Secondary study design
Qualitative study

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
Specialty: Children, Primary sub-specialty: Respiratory and Cystic Fibrosis; UKCRC code/ Disease: Infection/ Other viral diseases, Respiratory/ Other acute lower respiratory infections

Interventions

This study is a feasibility study to inform the design of a future trial of non-invasive ventilation (high flow nasal cannula (HFNC) and/or continuous positive air way pressure (CPAP)) in the management of children with bronchiolitis.

A systematic review is undertaken to identify outcomes used in bronchiolitis trials and how they are measured.

Eligible stakeholders are invited to participate with either: focus group workshop (health care professionals (n=80) and parents/carers (n=20); telephone/Skype software interviews (parents /carers only (n=15)) or a Delphi consensus survey (health care professionals (n=300) and parents /carers (n=34).

The workshops include three focus groups which covers identification and prioritisation of outcomes, trial design and consent (prospective and research without prior consent).

Parent telephone/Skype software interviews concentrate on identification and prioritisation of outcomes.

A list of collated outcomes identified from the systematic review, workshops and interviews are included into a Delphi survey. Stakeholders are asked to rate each outcome for importance on a Likert scale.

A national survey of practice are sent to lead paediatricians at NHS hospitals. The survey covers aspects of bronchiolitis management, criteria for initiating/weaning non-invasive ventilation and capability and capacity for running a clinical trial. In addition to the survey study sites are asked to complete a screening log to collect admission data over a four week period during the bronchiolitis season.

Stakeholders involved with either the workshops, interviews or Delphi survey are invited to attend an end of study event. The study data is presented to the attendees. The attendees are invited to participate in a final exercise to agree consensus over the future trial design and core outcome set.

Intervention Type
Other

Primary outcome measure
At the end of the NOVEMBR feasibility study, the trialists aim to be in a position to decide whether to proceed with a future definitive trial comparing different methods of non-invasive ventilation for managing children with bronchiolitis. If this is the case, a provisional study design and protocol will be written which is acceptable to important stakeholders. A bronchiolitis core outcome set will have been developed to improve standardisation, measurement and reporting of outcomes.This is done through stakeholder workshops, interviews and Delphi surveys.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
12/02/2016

Completion date

30/09/2018

Eligibility

Key inclusion criteria
1. Parents/carers of a hospitalised child (including emergency department (ED) attenders), aged 0-24 months, with a clinical diagnosis of bronchiolitis defined as per NICE Bronchiolitis Guidelines (2015): Diagnose bronchiolitis if the child has a coryzal prodrome lasting 1 to 3 days, followed by: persistent cough and either tachypnoea or chest recession (or both) and either wheeze or crackles on chest auscultation (or both)
2. HCPs who have at least six months experience in managing children diagnosed with bronchiolitis in the following clinical locations: ED, acute assessment unit, medical wards and critical care unit

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 115; UK Sample Size: 115

Key exclusion criteria
Parents/legal representatives who are unable to consent or unable to participate in the workshops or interviews in English. Due to the amount of planned topics to cover it would be impractical to conduct the workshop or interviews using an interpreter.

Date of first enrolment
12/02/2016

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alder Hey NHS Foundation Trust (lead centre)
Eaton Road
Liverpool

United Kingdom
L12 2AE

Study participating centre
Countess of Chester Hospital
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Arrowe Park Hospital
Arrowe Park Road
Upton Wirral
United Kingdom
CH49 5PE

Study participating centre
Royal Alexandra Children's Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Darlington Memorial Hospital Hollyhurst Road
Darlington
Darlington
United Kingdom
DL3 6HX

Study participating centre

Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

Sponsor details
Alder Hey Hospital
Eaton Road
West Derby
Merseyside
Liverpool
England
United Kingdom
L12 2AP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of the feasibility study will be presented at relevant national and international meetings and conferences (including the Royal College of Paediatrics and Child Health annual meeting), and will be submitted for publication in peer reviewed medical journals.

The developed bronchiolitis core outcome set will also be published on the Core Outcome Measures in Effectiveness Trials (COMET) initiative website: http://www.comet-initiative.org/

Protocol is currently being drafted for publication.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/11/2018		Yes	No
Results article	Core outcome set development results	09/03/2022	11/03/2022	Yes	No
HRA research summary			28/06/2023	No	No