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Hypertonic Saline in Acute Bronchiolitis

Submission date	Recruitment status	[X] Prospectively registered
15/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/09/2019	Respiratory	

Plain English summary of protocol

Background and study aims
Acute bronchiolitis is a common medical condition which affects children. It is caused by any of the common cold viruses, which cause the airways to become blocked, leading to difficulty breathing. The worst-affected babies require oxygen and help with feeding until they clear the virus themselves. Many treatments have been tried, but in all cases they were shown to be ineffective when properly tested. Saline is a common ingredient in nasal sprays, used to clear the airways of adults suffering with a cold. It has been suggested that inhaling a mist of 3% hypertonic saline (salt water) from a nebuliser (machine which converts liquid medication into a mist inhaled into the lungs) could be an effective way of treating acute bronchiolitis, and ensuring a quick recovery. The aim of this study is to find out whether nebulising infants suffering from acute bronchiolitis with 3% hypertonic saline can reduce the length of time that babies spend in hospital than standard supportive care.

Who can participate?
Infants under 1 year of age admitted to hospital with acute bronchiolitis who need oxygen therapy.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are nebulised with 3% hypertonic saline solution every 6 hours, as well as receiving standard supportive care and oxygen if required. Those in the second group receive standard supportive care and oxygen if required only. The time between admission and discharge from hospital is recorded for all participants. Participants in both groups are also followed up for 28 days, to monitor for any negative reactions (adverse events).

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Sheffield Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2011 to April 2012

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

Who is the main contact?
Professor Mark Everard
m.l.everard@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Mark Everard

Contact details
Department of Paediatric Respiratory Medicine
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH
+44 (0)114 271 7400
m.l.everard@sheffield.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT01469845

Protocol serial number
HTA 09/91/22

Study information

Scientific Title
Hypertonic Saline in Acute Bronchiolitis: a Randomised controlled trial and Economic evaluation

Acronym
SABRE

Study objectives
Comparing addition of nebulised hypertonic saline to usual supportive care in cohort of infants admitted with acute bronchiolitis.

1. Primary hypothesis is that the addition of 3% hypertonic saline to usual care results in significant (25%) reduction in the duration of hospitalisation of infants admitted with acute bronchiolitis.

2. Secondary hypotheses are that the addition of nebulised 3% hypertonic saline to usual care is associated with
2.1. Improved quality of life outcomes for carers
2.2. Shorter length of stay
2.3. Improved quality of life for infants
2.4. Reduced healthcare utilisation in the month after discharge
2.5. Cost-effectiveness for the NHS
2.6. The effect is independent of the underlying virus

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & the Humber - South Yorkshire on 24/05/2011

Study design
Multi-centre randomised controlled trial of a CE marked medical device.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute bronchiolitis

Interventions
Nebulised 3% hypertonic saline will be administered 6 hourly in the intervention group, in addition to standard supportive care, until the infant meets the pre-set criteria for discharge. A single use jet nebuliser with facemask (PARI Sprint with infant facemask); driven by piped oxygen will be used to administer the hypertonic saline. The control arm will receive standard supportive care.

Total duration of follow-up will be 28 days from entry to study.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hypertonic saline

Primary outcome(s)
Current primary outcome measures as of 27/10/2011:
1. Time to fit for discharge, which will be judged to be when the infant is feeding adequately (taking more than 75% of usual intake)
2. Has been in air with a saturation of at least 92% for 6 hours, to reflect clinical practice.

Previous primary outcome measures:
2. Has been in air with a saturation of 94% or greater for 12 hours

Key secondary outcome(s)
1. Actual time to discharge
2. Readmission within 28 days from randomisation
3. Health care utilisation, post-discharge and within 28 days from randomisation
4. Duration of respiratory symptoms post discharge and within 28 days from randomisation
5. Infant and parental quality of life using the Infant Toddler Quality of Life (ITQoL) questionnaire at 28 days following randomisation.

Completion date
30/04/2012

Eligibility

Key inclusion criteria
Previously healthy infants under 1 year of age admitted to hospital with a clinical diagnosis of acute bronchiolitis, following the UK definition.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Wheezy bronchitis or asthma children with an apparent viral respiratory infection and wheeze with no or occasional crepitations
2. Previous lower respiratory tract infections
3. Risk factors for severe disease (gestation < 32 weeks, immunodeficiency, neurological and cardiac conditions)
4. Participation in another study involving investigational medication
5. Subjects where the carers English is not fluent and translational services are not available
6. Requiring admission to high dependency or intensive care units at the time of recruitment

Date of first enrolment
15/10/2011

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Children's Hospital
Department of Paediatric Respiratory Medicine
Western Bank
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Sheffield Children's NHS Foundation Trust (UK)

ROR
https://ror.org/02md8hv62

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) - HTA (UK) (09/91/22)

Results and Publications

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?
Results article	results	01/12/2014		Yes	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes