

Hypertonic Saline in Acute Bronchiolitis

Submission date 15/02/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/09/2019	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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
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Study website
<http://www.shef.ac.uk/scharr/sabre>

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01469845

Secondary identifying numbers
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

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 below to request a patient information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

15/10/2011

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

Age group

Neonate

Sex

Both

Target number of participants

Updated 27/10/2011: 300 in total across 9 centres (8 centres at time of registration)

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**

England

United Kingdom

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)

Sponsor details

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+44 (0)114 271 7417

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Sponsor type

Hospital/treatment centre

Website

<http://www.sheffieldchildrens.nhs.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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