Hypertonic Saline in Acute Bronchiolitis RCT and Economic Evaluation

The SABRE study is a randomised controlled trial and economic evaluation of hypertonic saline in acute bronchiolitis in babies, taking place in nine NHS hospitals around the UK. It aims to determine whether the addition of nebulised 3% hypertonic saline to usual care results in significant (25%) reduction in the duration of hospitalisation of babies admitted with acute bronchiolitis. If the treatment is found to be effective it will be the first shown to influence the natural history of this common and very important disease.

Target population: Infants less than 12 months of age admitted to hospital with a clinical diagnosis of acute bronchiolitis and requiring supplemental oxygen on admission as part of routine supportive care.

Health Technology to be assessed: The addition of nebulised 3% hypertonic saline to usual care. This treatment will be administered 6 hourly until the infant meets the pre-set criteria for discharge.

Outcomes and measurement of cost:

Primary outcome

The primary outcome will be time to 'fit for discharge', which will be judged to be when the infant is feeding adequately [taking >75% of usual intake] and has been in air with a saturation of at least 92% for 6 hours.

Secondary outcomes

- Actual time to discharge
- Readmission within 28 days from randomisation
- Health care utilisation, post-discharge and within 28 days from randomisation
- Duration of respiratory symptoms post discharge and within 28 days from randomisation using a symptom diary
- Infant and parental quality of life using the Infant Toddler Quality of Life (ITQoL) questionnaire at 28 days following randomisation.

Staff input: Parents of babies under one year old admitted with acute bronchiolitis will be approached and consented by GCP-trained **Specialty Trainee (ST 1-8) paediatricians and consultants, or staff of equivalent training** (e.g. GCP-trained paediatric nursing staff responsible for acute admissions). The baby will be "randomly allocated" via a password protected web-based system to receive either: a) nebulised hypertonic saline in addition to usual care or b) continue with usual care. No additional data collection will be required by the medical or nursing staff.

Data collection: Research nurses will record baseline demographic data, co-interventions, and outcome data. On discharge the parents will be asked to keep a diary of symptoms up to 28 days and to complete a questionnaire at 28 days post-randomisation, and research nurses will provide follow-up over the telephone.

Study training: Study training will be provided by the Sheffield research team for all middle grade doctors and nurses who may be recruiting and consenting to the study. Staff who will be recruiting and consenting participants to the trial will also receive Good Clinical Practice training, as this is a requirement for research studies.

The study recruited participants during the winters of 2011/12 and 2012/13 and is aiming to recruit further participants from October 2013 to December 2013, with a total target of 300 patients across nine NHS sites overall. It is managed by the Clinical Trials Research Unit (CTRU) at Sheffield University, and funded by the NIHR Health Technology Assessment Programme.

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