• The DAB Trial •

(Dexamethasone Adrenaline in Bronchiolitis)

Project title

Randomised controlled trial of a combination of Dexamethasone and Adrenaline for Bronchiolitis

Study investigators
Ben Gelbart Frank Shann Carmel Delzoppo Warwick Butt Siva Namachivayam

Study contract: Ben Gelbart: ben.gelbart@rch.org.au

Aim
To determine whether parenteral dexamethasone and nebulised adrenaline reduce the duration of positive pressure support in children admitted to the intensive care unit with bronchiolitis.

Brief background
Bronchiolitis is an acute infection of the lower respiratory tract, characterised by rhinorrhea, cough, wheezing, respiratory distress and hypoxemia. Many viruses cause this collection of signs and symptoms. The most common causative organism is respiratory syncytial virus (RSV), however parainfluenza, adenovirus and influenza can also cause bronchiolitis. Bronchiolitis is the leading cause of hospitalisation during the first year of life; it accounts for 21% of all hospital admissions in children under 1 year of age, and is a major cause of morbidity and mortality in children. Victorian state-wide data for the calendar year 2006 revealed 2280 admissions for bronchiolitis, with an average length of stay of 3.2 days and 186 (7.4%) patients admitted to intensive care. Bronchiolitis hospital admissions in Victoria in 2006 are estimated to have cost $8.1 million. In the United States, annual hospital costs for RSV-associated bronchiolitis were estimated to be $365 million to $691 million in 1998. Over 1500 children present to the Royal Children's Hospital Emergency Department every year with bronchiolitis, with approximately 500 children admitted to hospital and 100 admitted to the Paediatric Intensive Care Unit (PICU).

The treatment of bronchiolitis is controversial. Many studies have looked at possible treatments for bronchiolitis, with the most commonly investigated being bronchodilators, adrenaline and corticosteroids. Few treatments have demonstrated any clinical benefit to patients, and several bronchiolitis treatment guidelines recommend no pharmacological treatments at all. Despite this lack of evidence, patients continue to be treated with a range of interventions including adrenaline. bronchodilators, antibiotics and corticosteroids with evidence to suggest that treatment is given independent of the severity of the illness. Given the vulnerable population that presents with bronchiolitis, it is important that practice is based on sound evidence.

Description of the study:

The study is a randomised controlled trial conducted in Melbourne Perth and New Zealand. Patients with bronchiolitis admitted to the intensive care with bronchiolitis and respiratory distress will be eligible. The interevention will be parenteral dexamethasone and nebulised adrenaline followed by ongoing prednisolone and nebulised adrenaline until patient discharge from the intensive care. Standard care will also be provided. The control group will receive standard care alone. The trial will be unblinded. The primary outcome is whether there is a difference in duration of positive pressure support ventilation. Secondary outcomes will include duration of mechanical ventilation, intensive care length of stay, hospital length of stay, rate of intubation and pressure-rate product if a nasogastric tube is already in situ. The pressure-rate product is a way of measuring the strain on the lung.

Randomisation will occur via an online website.

Eligibility

Inclusion criteria

- a clinical diagnosis of bronchiolitis, defined as a first or second episode of wheezing or respiratory distress associated with a respiratory tract infection plus either radiological evidence of chest hyperinflation or clinical evidence of prolonged expiration
- less than 18 months of age
- no previous admission to this study
- admission to intensive care for respiratory distress (not apnoea alone)
- recruitment and initiation of the study therapy within 4 hours of admission to intensive care

Exclusion criteria

- Corrected gestational age of less than 36 weeks at time of admission to the intensive care.
- Clinical evidence of croup (laryngotracheobronchitis)
- Immunosuppressive treatment, including any dose of corticosteroids in the last 7 days.