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Title: Effect of high dose inhaled beclomethasone for respiratory syncytial virus bronchiolitis during infancy on lung function and asthma at age 6 – A randomised placebo-controlled trial

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Body: Background: Respiratory syncytial virus (RSV) bronchiolitis is the most common cause for hospitalization in infants, and is associated with preschool wheeze. However, the relationship between RSV bronchiolitis hospitalization and long-term airway disease is controversial. Methods: This is a 6-year follow-up report of a RCT, in which 185 infants, hospitalized for RSV bronchiolitis were treated with early initiated, high dose inhaled beclomethasone (n=86) or placebo (n=99) for 3 months. The primary outcome was FEV1%predicted. Secondary outcomes were bronchial hyperresponsiveness, physician diagnosed asthma, hay fever and eczema, and linear growth. Measures were compared to an unselected healthy birth cohort study (n=579). Results: At age 6, no significant differences were found in mean FEV1 %predicted between beclomethasone-treated and placebo-treated patients (91.4 v 93.4, mean difference 2.05 (95% CI -1.98 to 6.08). Physician diagnosed asthma, parent reported hay fever and eczema were comparable between groups, as was linear growth. Compared to healthy controls the RSV group had lower FEV1 %predicted, 92.4% v 100.1%, mean difference -7.68% (95% CI -10.21 to -5.14), more often physician diagnosed asthma, 22.7% versus 5.4%, RD 17.4% (95% CI 11.0 to 23.6) while similar proportions of atopic diseases. Conclusion: Treatment with high dose inhaled beclomethasone did not improve the long-term respiratory outcome of hospitalized infants with RSV, but was safe. Hospitalization for RSV infection is associated with a lower lung function and increased risk of physician diagnosed asthma at age 6.