

European Respiratory Society Annual Congress 2012

Abstract Number: 4275

Publication Number: P2948

Abstract Group: 7.4. Paediatric Respiratory Infection and Immunology

Keyword 1: Infants **Keyword 2:** Infections **Keyword 3:** Bronchodilators

Title: Inhaled racemic adrenalin versus saline in acute bronchiolitis, a multicenter randomized double-blind clinical trial

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Body: Background: The efficacy of inhaled racemic adrenaline (iRA) versus general supportive therapy in acute bronchiolitis in infants is questioned. Aims: To assess efficacy of iRA versus inhaled saline and regular vs. on demand therapy in hospitalized infants with acute bronchiolitis. Subjects and methods: A multicenter (n=8) randomized double-blind controlled trial (pharmaceutical company independent) of iRA vs saline further randomised into regular vs on demand inhalations (up to every second hour) included 404 children < 12 months of age (mean 4.2 months), 59.3% boys, with moderate to severe acute bronchiolitis in Norway in 2009-11. A validated clinical score (0-10, 0 best) was used pre-and post inhalation daily. Inclusion required a score ≥ 4 . Supportive therapy (oxygen, nasogastric feeding (NGf) or ventilatory support) were recorded. The primary outcome was length of stay (LOS) (hours until deemed ready for discharge). Analyses were by intention to treat except for LOS. Results: Infants treated with iRA vs saline had no significant difference in LOS (mean, 95% conf. interval)(59.6, 52.2–67.0 vs 63.6, 56.2-71.0) (n=322) (p=0.4) or need for NGf (21.8 vs 24.4%), ventilatory support (7.4 vs 7.5%), supportive treatment (27.2 vs 25.9%) or

relative improvement in clinical score from pre-inhalation (0.25 vs 0.22) (all $p > 0.1$, $n = 40$). On demand vs regular study medication inhalations resulted in shorter mean LOS (54.93, 47.9-62.0 vs, 68.1, 60.4-75.7 hrs, $p = 0.01$) and fewer inhalations (11.9 vs 17.0) ($p < 0.001$). Conclusion: Inhaled RA for acute bronchiolitis is not more effective than inhaled saline, whereas inhalations on-demand appears more effective than regular intervals.