Azithromycin does not improve disease course in hospitalized infants with respiratory syncytial virus (RSV) lower respiratory tract disease: An randomized equivalence trial.

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BACKGROUND: Nearly half of all hospitalized infants with respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) are treated with (parenteral) antibiotics. The present study was designed to test our hypothesis that the use of antibiotics would not lead to a reduced duration of hospitalization in mild to moderate RSV LRTD.

METHODS: Seventy-one patients <=24 months of age with a virologically confirmed clinical diagnosis of RSV LRTD were randomized to azithromycin 10 mg/kg/day (n = 32) or placebo (n = 39) in a multicenter, randomized, double-blind, placebo-controlled equivalence trial during three RSV seasons (2002-2004 through 2005-2006). Primary endpoint was duration of hospitalization, secondary endpoints included duration of oxygen supplementation and nasogastric tube feeding, course of RSV symptom score, number of PICU referrals and number of patients who received additional antibiotic treatment. Data were analyzed according to the intention-to-treat principle using the Mann-Whitney U-test or chi(2) test considering P < 0.05 as statistically significant.

RESULTS: Included patients were comparable with respect to baseline demographics, clinical characteristics, laboratory and roentgenologic investigations. The mean duration of hospitalization was not significantly different between patients treated with azithromycin or placebo (132.0 +/- 10.8 vs. 139.6 +/- 7.7 hr, P = 0.328). Azithromycin was not associated with a stronger resolution of clinical symptoms represented by the RSV symptom score. Four patients were treated with antibiotics after 72 hr, three of them were assigned to placebo (P = 0.406). CONCLUSIONS: Infants and young children with RSV LRTD do not benefit from routine treatment with antibiotics (ISRCTN number 86554663). Pediatr Pulmonol. (c) 2007 Wiley-Liss, Inc.

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