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Title: Systemic activity of two different dry powder combinations of inhaled corticosteroids and long-acting β2-agonists in children with asthma assessed by knemometry

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Body: RATIONALE: A combination of the inhaled corticosteroid budesonide and the long-acting β2-agonist formoterol has been formulated in a novel dry powder inhaler, Spiromax®. OBJECTIVE: To compare lower leg growth in children with asthma treated with inhaled budesonide+formoterol (BF) delivered from the Spiromax inhaler with BF from the Symbicort Turbohaler®. METHODS: Prebubescent children with persistent asthma (n=75, ages 6-11 years) were included in a randomised, double-blind, double-dummy, placebo controlled, three-way crossover study with active treatment and placebo periods of 2 weeks duration. Lower leg length was measured by knemometry. Interventions were inhaled BF 120+9 µg bid delivered from the Spiromax inhaler and BF 200+12 bid µg from the Symbicort Turbohaler. RESULTS: The LS mean difference in lower leg growth rates between BF Spiromax and Symbicort Turbohaler was -0.086 mm/week (95% confidence interval (CI) -0.203, 0.032). The pre-specified non-inferiority margin was -0.200 mm/week, so, the lower limit of the 95% CI was just outside this margin. The difference between Spiromax and placebo was -0.20 mm/week (95% CI: -0.322, 0.086); P<0.001), between Symbicort Turbohaler and placebo -0.118 mm/week (95% CI: -0.236, -0.001; P=0.048). CONCLUSIONS: The lower limit of the confidence interval was only marginally outside of the prespecified non-inferiority margin. Further studies may be needed for comparison of systemic activity of Spiromax and Symbicort Turbohaler before firm conclusions may be drawn. Research funding source: TEVA Branded Pharmaceutical Products R&D, Inc., Miami, USA.