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Intermittent Tiotropium Bromide for Episodic Wheezing: A Randomized Trial

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CONFLICT OF INEREST DISCLOSURES: The authors have indicated they have no conflicts of interest to disclose.This trial is registered at EudraCT (identifier, 2015-002985-22) and ClinicalTrials.gov (identifier, NCT03199976).

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BACKGROUND AND OBJECTIVES:

Options to treat and prevent episodic wheezing in children are scarce. Our objective was to assess the efficacy of intermittent tiotropium bromide treatment in early childhood episodic wheezing.

METHODS:

This 48-week, randomized, open-label, controlled, parallel-group trial was conducted at 4 hospitals in Finland. Children aged 6 to 35 months with 2 to 4 physician-confirmed episodes of wheeze and/or shortness of breath were considered eligible. Study participants were randomly allocated to receive 1 of 3 treatments: once-daily tiotropium bromide 5 μg for 7 to 14 days during respiratory tract infections and as-needed albuterol sulfate 0.2 mg (n = 27), twice-daily fluticasone propionate 125 μg for 7 to 14 days during respiratory tract infections and as-needed albuterol

sulfate 0.2 mg (*n* = 25), or as-needed albuterol sulfate 0.2 mg alone (*n* = 28). The primary outcome was efficacy, assessed as intention-to-treat by comparing the proportion of episode-free days (the days lacking symptoms or treatments) between the treatment groups.

RESULTS:

The proportion of episode-free days was higher in those receiving intermittent tiotropium bromide (median 97% [interquartile range, 93% to 99%]) than in those receiving intermittent fluticasone propionate (87% [78% to 93%], *P* = .002), or with as-needed albuterol sulfate alone (88% [79% to 95%], *P* = .003). Adjustment with allergic sensitization, the baseline number of physician-confirmed episodes of wheeze and/or shortness of breath, or short-course glucocorticoid treatment in the 2 weeks before the enrollment, did not affect the result. Intervention-related adverse events were not seen.

CONCLUSIONS:

Intermittent tiotropium bromide treatment may be an effective alternative to current therapies for episodic wheezing. Before implementation of use, further research on safety and efficacy is indicated.

Subjects: Respiratory Tract

Topics: tiotropium bromide, wheezing, albuterol, sulfate, fluticasone, tiotropium

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