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MEETING ABSTRACT Open Access

Asthma diagnosis and treatment – 1012. The efficacy of budesonide in the treatmetn of acute asthma in children: a double-blind, randomized, controlled trial

Abdullah A Alangari[1*], Nidal Malhis[2], Mohamed Mubasher[3], Najwa Al-Ghamdi[4], Mohammed Al-Tannir[5], Mohammed Riaz[5], Dale Umetsu[6], Saleh Al-Tamimi[2]

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Background

Current evidence suggests that inhaled glucocorticoids (IGC) have a more profound topical none genomic effect on bronchial airways as compared to systemic glucocorticoids. The value of adding IGC to current therapy of acute asthma is not well established.

Methods

We conducted a double-blind, randomized, two-arm, parallel groups, controlled clinical trial to compare the addition of budesonide 1500 mcg or placebo (normal saline) to standard acute asthma treatment (albuterol and ipratropium bromide) administered in 3 divided mixed doses within 1 hour in the emergency department (ED). Children 2-12 years of age with moderate or severe acute asthma, scoring 8-15/15 on a well-validated scoring system were included. Both groups received a single dose of prednisone 2 mg/kg/day (max. 60 mg) at the beginning of therapy. The primary outcome was admission rate within 2-4 hours from starting therapy.

Results

A total of 723 children were enrolled in the study over 17 months duration, of whom 139 were allowed to re-enroll and be randomized to constitute 906 randomization assignments (458 on the treatment group and 448 on the control group); with baseline mean + SD asthma score of 10.63 + 1.73; age 5.52 + 2.76 years; 35% girls; 30.8% (16.5%) with baseline severe asthma score of ≥12 (≥ 13). Statistical Analysis plan allowed for the potential dependency in response due to reenrollments of a subset of children, using Generalized Linear Mixed Modeling (GLMM) techniques. Baseline demographic and clinical characteristics were not significantly different between the two randomized groups. Seventy-five out of 458 (16.4%) of the treatment group vs. 82/448 (18.3%) of the control group were admitted, (OR 0.85, CI: 0.59-1.23, p-value=0.39). Among the severe asthmatics with baseline score ≥13, treatment vs. placebo group, GLMM adjusted admission rate was 30% vs. 47%, indicating a 17% difference in admission rate in favor of the treatment group (adjusted OR of 0.49, CI: 0.25-0.95; p-value= 0.035) that indicated a 51% reduction in the risk of admission for the treatment vs. control group.

Conclusions

Children with baseline severe asthma score ≥13 who were treated with budesonide had a significant reduction in their admission rate.

[1]Pediatrics, King Saud University, College of Medicine, Riyadh, Saudi Arabia
Full list of author information is available at the end of the article

Author details
[1]Pediatrics, King Saud University, College of Medicine, Riyadh, Saudi Arabia. [2]Emergency Medicine, King Fahad Medical City, Riyadh, Saudi Arabia. [3]King Fahad Medical City, Saudi Arabia. [4]Pharm D , Pharmacy, King Fahad Medical City, Riyadh, Saudi Arabia. [5]King Fahad Medical City, Riyadh, Saudi Arabia. [6]Harvard University, MA, USA.

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