

Fluticasone furoate for inadequately controlled asthma**To the Editor:**

Oliver et al¹ sought to demonstrate the efficacy, dose response, and safety of fluticasone furoate in children with poorly controlled asthma. We urge cautious interpretation of the methodology and results. The description of this sample population was unclear, limiting applicability. The study question was also unclear, with the suggestion of improving compliance with a once daily medication remaining unaddressed. The primary outcome was revised after data collection, prompting us to question the amount of missing data identified from the original primary outcome. Furthermore, we questioned the reliability of peak expiratory flow in the younger children in this study.

Although statistical “significance” for the primary outcome was reported for all treatment groups compared with placebo, this did not adequately address the stated aims of the study (dose response, safety, and efficacy) or address the question of compliance. Post hoc analysis of secondary outcomes was also a concern.

Significant dropout across all treatment groups at 29%, compromised the validity of the results. Furthermore, the use of dropout data to suggest a treatment effect was overstated. Power calculations for the 25 mcg dose were omitted, despite the data for this group being included. Finally, there was no discussion of compliance or control for inhaler

technique and different types of inhaler may have compromised blinding.

In summary, the authors presented an industry-sponsored trial, with an unclear question, overly complicated by multiple drug doses, comparisons only with placebo and a revised primary outcome. As such, the applicability and reliability of the data is compromised.

Julian Dascalu, MD

Department of General Medicine
Royal Children's Hospital
Melbourne, Victoria, Australia

Susan Donath, PhD

Clinical Epidemiology and Biostatistics Unit
Murdoch Children's Research Institute
Melbourne, Victoria, Australia

Georgina Tiller, MBBS

Department of General Medicine
Royal Children's Hospital
Melbourne, Victoria, Australia

Reference

1. Oliver AJ, Covar RA, Goldfrad CH, Klein RM, Pedersen SE, Sorkness CA, et al. Randomized trial of once-daily fluticasone furoate in children with inadequately controlled asthma. *J Pediatr* 2016;178:246-53.