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**Title:** Efficacy of the Plasma Cluster® device in mild to moderate asthmatic children: A randomized, double-blind, placebo-controlled, proof-of-concept trial

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**Body:** Background Asthmatic children are commonly sensitized to the house-dust mite. Effective environmental control can modify disease activity in patients. According to Japanese pediatric guidelines for asthma(JPGL), enough house cleaning and beddings are recommended. However, as to the efficacy of any air cleaning devices for the house, JPGL does not mention this matter due to lack of evidence. Objectives To examine the efficacy of an air cleaning device (PC; Plasma Cluster® device / Sharp Corp., Japan) in reducing airway inflammation in asthmatic children. Methods The study was a randomized, double-blinded, placebo-controlled, and crossover study. Patients were randomized to PC or placebo device for 8 weeks, exchanging their devices for a further 8 weeks after a 2-week wash-out period. Asthma symptom diary and PEFr measurement data were recorded. FeNO measurements were taken at start of the study, 4 weeks and 8 weeks of each period. The primary outcome was to see changes in FeNO levels. Patients enrolled in the study were mild to moderate asthmatic children seen at our department. Written informed consent was obtained from all caregivers. The study was conducted from August to October of 2011. This study registered with UMIN Clinical Trials Registry, UMIN000006354. Results 32 patients (M:F=22:10, 10.2±3.1 years) were enrolled. Significant effect of PC device to reduce FeNO levels in the subjects was not shown by a generalized linear mixed model (p<0.06). Conclusion The results of this study provide positive proof of concept for efficacy of the PC device and show measuring FeNO levels can be an adequate outcome in comparison with the others.