

## Clinical Trial: Effect of IQAir® Air Cleaners on Asthmatic Children Sensitised to Pet Allergens

### Comments by INCEN AG

This clinical trial shows remarkable results. Not only was it shown that the use of IQAir® HyperHEPA® filtration systems could halt the deterioration of allergy symptoms, but that they can also lead to a reduction in symptoms. It is especially noteworthy that IQAir® achieves this result without any short or long-term side effects which are often observed with allergy drugs. This clinical trial also supports the results by the independent German consumer test agency *Stiftung Warentest* in 1998, which recommended IQAir® as the best air cleaner for respiratory allergies.

Some further analysis of the blood tests (ECP) from the Norwegian part of the study by the Dept. for Asthma, Allergy and Chronic Lung Disease at the National Hospital's Paediatric Clinic has produced evidence that the patients with active filters had better ECP results than the patients with sham filters. Since ECP is an accurate method of evaluating disease activity in allergic patients, this finding is very important in showing the beneficial effect of IQAir®.

As a world-leading manufacturer of advanced air-cleaning systems with some 40 years of experience in indoor air filtration, INCEN AG feel strongly about investing in scientific research and development. The outcome of this landmark clinical trial proves that our continuous investment in scientific research and the emphasis we place on quality and actual filtration performance have been worthwhile goals to pursue. As a result, INCEN AG is able to offer the world's most professional HEPA air cleaning solutions for individuals with respiratory allergies.

**Our particular thanks go to the German and Norwegian scientists and all the patients for their valuable contribution to this large and complex 1-year clinical trial.**

## Clinical Effects of High-Performance Air Cleaners and Mattress Covers in Homes of Asthmatic Children and Adolescents Sensitized to Cat or Dog Allergens

### A report of a German indoor allergen avoidance study as a measure of tertiary prevention.

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#### Background

Exposure and sensitisation to pet allergens is associated with allergic asthma in childhood. Avoidance of pet allergens in these patients is the first line of treatment in addition to pharmacotherapy. While primary prevention means the prevention of the development of sensitisation and allergic disease, secondary prevention means the development of allergic airway disease if sensitisation has already occurred. Tertiary prevention means avoidance of exacerbation of ongoing allergic disease and avoidance of chronification and deterioration of an inflammatory process.

The most important sources of indoor pet allergens are cat and dog allergens. As a large percentage of pet allergens remain airborne due to their small size, simple cleaning procedures as wiping, vacuuming floors and surfaces of beds and furniture are not enough to effectively reduce allergen exposure in patients' homes. Conflicting data have been reported about the clinical benefit of air cleaners being placed in patients' homes.<sup>1,2</sup> Certified HEPA filter systems (high efficiency particulate arresting) are known to remove 99.97% of airborne cat allergens in filtered air.

In order to evaluate the clinical effect of IQAir® air cleaners (INCEN AG, Switzerland) a study was conducted investigating bronchial hyper-responsiveness (BHR) in 31 asthmatic children over a 1-year period.

#### Methods

In a randomised, controlled trial 35 asthmatic children (aged 6–17 years) with sensitisation to cat and/or dog allergens were included in order to study the effects of HEPA air cleaners (IQAir®, INCEN AG, Goldach, Switzerland) placed in living and bed rooms and allergen impermeable mattress encasings (Dr. Beckmann, Germany) compared with the effect of sham air cleaners and encasing. 31 patients completed the investigation. 60% of the families kept pets. All homes showed major allergen exposure (Fel d1 from cat or Can f1 from dog) > 500 ng/g carpet dust. Patients were allocated into 4 groups.

- Group 1: active filter, active mattress encasing (n=9) (V/V)
- Group 2: active filter, sham encasing (n=8) (V/P)
- Group 3: sham filter, active encasing (n=6) (P/V)
- Group 4: sham filter, sham encasing (n=8) (P/P)

Mattress encasings were given to patients within controlled study design. Active encasings were polyurethane covered, sham encasings were made of simple cotton fabric. This design was chosen in order to study both the effects of certified HEPA air cleaners and mattress encasings in pet allergic asthmatic patients. 60 % of patients kept either dogs or cats. All patients were found to have initial FEV1 above 60% predicted. At day 0, after 6 and 12 months pulmonary function testing and cold air challenge tests were performed, serum ECP (eosinophil cationic protein) and specific serum IgE to 7 inhalant allergens (birch, grass pollen, house dust mite *Dermatophagoides pteronyssinus*, cat, dog, *cladosporium herbarum*, mugwort) were determined and mattress and carpet dust samples were collected. Major pet allergens (Fel d 1 and Can f 1) were measured in filters and bulk dust samples. Clinical symptoms scores were monitored at every visit, consumption of medication was recorded monthly.

Endpoints of the study were:

1. Change in FEV1 after cold air challenge (delta FEV1 pre and post cold air challenge)
2. Decrease in clinical symptoms score
3. Amount of retained major pet allergen in filters and bulk dust samples.

## Results

After 6 and 12 months, FEV1 improved in all 4 groups ( $p < 0.01$ ), appearing to be a general effect of participating in a study. There was no significant change in eosinophil cationic protein (ECP) values and use of medication, however, there was a trend that nasal (stuffy nose) and nocturnal symptoms (cough and shortness of breath) decreased in the active group ( $p < 0.05$ ).

In the active group, delta FEV1 (comparing FEV 1 pre and post cold air challenge) was decreasing during the study period, meaning that bronchial hyper-responsiveness was decreasing due to the reduction of allergens in patients' homes. Figure 1 demonstrates data for all 4 subgroups, Figure 2 shows the combined evaluation of the 2 subgroups with active cleaners and the 2 subgroups with sham air cleaners. Figure 4 shows in a different way that the fall in FEV1 after cold air challenge diminishes in the active group. In the group with sham cleaners there was a slight but insignificant increase in bronchial hyper-responsiveness during the study period. Mattress encasings did not achieve any additional benefit for the patients.

While the sham cleaners were not found to retain allergens, the active filters were found to contain very high Fel d1 and Can f1 concentrations (Figure 5 and 6). They obviously removed large amounts of pet allergens from the air.

## Discussion

Elimination of indoor allergens as a measure of secondary and tertiary prevention is important in patients with allergic airway disease. The efficacy of HEPA filters in this study was not as high as expected, however, clear beneficial trends were observed. One reason may be that patients did not strictly follow the recommendation to turn on air filters for 24 h every day. Some patients reported that they prefer sleeping without any noise and turned off filters during nighttime. Another confounder was consumption of medication. Half of the patients received steroids to inha-le which might have masked a potential significant influence on bronchial hyper-responsiveness due to air cleaning. However, our results are in accordance with a British study, having also demonstrated a small but significant improvement in combined asthma outcome in adult asthma patients sensitised and exposed to cats or dogs.<sup>3</sup>

## Conclusion

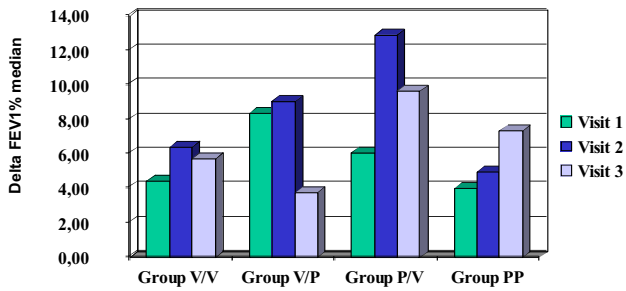
- The IQAir® air cleaners with HEPA filters retain a significant amount of airborne pet allergen.
- Patients with active cleaners showed a slight reduction in BHR after 6 and 12 months, while the control group showed a slight increase in BHR.
- IQAir® air cleaners can be a useful measure of tertiary allergen avoidance in sensitised asthmatic patients.

## References

1. Van der Heide et al. *Clinical effects of air cleaners in homes of asthmatic children sensitized to pet allergens.* *J Allergy Clin Immunol* 1999; 104: 447-51.
2. Wood RA et al. *A placebo-controlled trial of a HEPA air cleaner in the treatment of cat allergy.* *Am J Respir Crit Care Med* 1998; 158: 115-20.
3. Francis H, Fletcher G, Anthony C, Pickering C, Oldham L, Hadley E, Custovic A, Niven R. *Clinical effects of air filters in homes of asthmatic adults sensitized and exposed to pet allergens.* *Clin Exp Allergy* 2003; 33: 101-5.

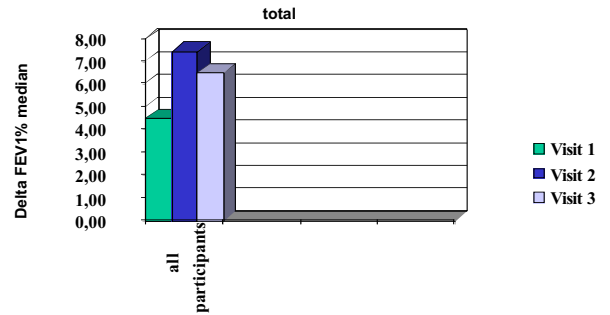
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BHR in different treatment groups at different times



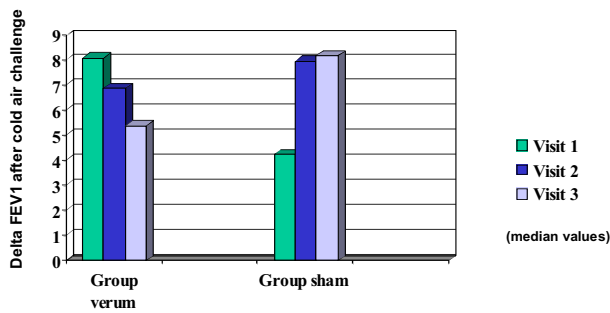
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BHR in different treatment groups at different times



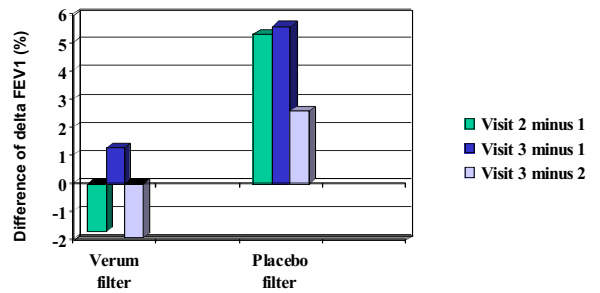
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BHR: active versus sham filter



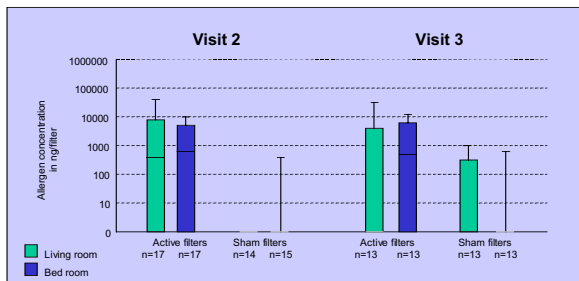
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Change of delta FEV1(pre-post challenge)



5

Fel d 1 (cat) allergen concentrations in HEPA-filters



6

Can f 1 (dog) allergen concentrations in HEPA-filters

