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Letter to the editor

Atopic dermatitis, house-dust mite, and the placebo effect

We read with great interest the paper of Holm et al. (1) in the February issue of this journal. The authors have performed a very thorough, placebo-controlled, prospective study on the effect of house-dust-mite (HDM) elimination in patients with atopic dermatitis (AD). We appreciate this laborious work over the period of a whole year, and, in fact, there was a need for this study because the studies published before did not focus on the population investigated by Holm et al., namely, only adult patients with AD. We have performed a similar investigation, and we did not observe a clinical effect of HDM control measures on the skin status of adult AD patients (2).

Holm et al. observed improvement of the skin status of AD patients treated by occlusive bedding. However, the results did not differ significantly from the placebo group. Interestingly, patients not sensitized to HDM and not exposed to HDM allergens benefited equally from the use of the bedcovers. Analysis of the subgroup with sensitization to *Pityrosporum orbiculare* revealed a significantly greater eczema reduction in the active treatment group than the placebo group. In conclusion, the authors recommend the use of bedcovers as part of the treatment for AD.

However, we do not agree with this conclusion since the main finding of this study is that, with respect to the skin status, there was no significant difference between the active and control groups. Therefore, the results of this investigation cannot be the basis for the recommendation of occlusive bedding as a part of AD treatment.

A post hoc subgroup analysis, as performed here, regarding the sensitization to *P. orbiculare* is not warranted, according to the ICH E9 guideline (3). This guideline recommends that an analysis of subgroup effects be an integral part of the planned analysis, and hence be set out in the protocol; as a consequence, stratified randomization is required. Otherwise, such a post hoc analysis is considered to be an exploratory analysis that is unlikely to be accepted, especially as the mattress concentration of *P. orbiculare* has not been investigated.

Another finding of the study is that patients not sensitized to HDM and not exposed to HDM allergens benefited equally from the use of the different bedcovers. The authors state that this result could be due to a reduction by mattress encasing of other important superantigens or irritants in the bed. Unfortunately, the authors have not investigated this hypothesis, which, we think, is rather unlikely, at least for staphylococci, since they directly colonize the skin (4) and thus cannot be removed by this method.

The authors should have considered the possibility that a mere placebo effect was responsible for their results. The placebo effect can be dramatic in AD, as shown by another HDM study (4).

We therefore conclude from the authors' findings that there is no evidence for a clinical effect of occlusive bedding on the skin status of adult patients with AD, a conclusion which is in line with the results of our own study (2).

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