

RECRUITMENT OF NON-ALLERGIC VOLUNTEERS FOR HUMAN EXPERIMENTAL INHALATION STUDIES: DOES THE OUTCOME JUSTIFY THE EFFORT?

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Question

Non-allergic healthy individuals aged 18-55 years are needed for human experimental inhalation studies. The suitability of volunteers was checked by questionnaire and a broad medical baseline investigation.

Methods

A total of 105 volunteers (median: 24 (19-37) years; 56% female) not reporting respiratory allergies participated in the baseline investigation including physical examination, skin prick test (SPT) to 9 ubiquitous allergens, measurements of total IgE, specific IgE (sIgE) to an ubiquitous allergen mix (sx1), fractionated exhaled nitric oxide (FeNO) as well as pulmonary function test and methacholine test.

Results

The median value for sIgE to sx1 was 0.20 kU/L (0.07-91.3 kU/L) and correlated significantly with total IgE (28.8 kU/L (2-756 kU/L) and FeNO values (13 ppb (5-94 ppb)). 43 subjects (41%) had sIgE to sx1 \geq 0.35 kU/L and were classified as atopic. 35 subjects, all of them also sx1-positive, showed at least one positive SPT reaction. Obstruction, small airway disease, and/or bronchial hyperreactivity were diagnosed in 18 subjects. To check whether signs of sensitization are useful to discriminate subjects with and without airway diseases, receiver operator characteristics (ROC) were performed. However, sx1, total IgE, FeNO and SPT reached only low areas under the curve (AUC: 0.57-0.66).

Conclusion

Although predominantly young and according to self-reported statements non-allergic subjects participated in the baseline investigation, almost half of them showed signs of atopy and 10% even airway disease/bronchial hyperreactivity. With the exception of SPT, all investigations seem to be necessary for a successful recruitment of non-allergic healthy study participants.