

RECRUITMENT OF HEALTHY VOLUNTEERS FOR HUMAN EXPERIMENTAL STUDIES: HOW HEALTHY IS HEALTHY?

D. Rosenkranz, J. Bünger, F. Hoffmeyer, C. Monsé, B. Jettkant, V. van Kampen, M. Raulf, T. Brüning and K. Sucker

Research Institute for Prevention and Occupational Medicine of the German Social Accident Insurance (IPA), Institute of the Ruhr University Bochum, Bürkle de la Camp-Platz 1, 44789 Bochum, Germany, sucker@ipa-dguv.de

Question

Human experimental studies are usually performed on healthy volunteers. In order to assess medical suitability, screening by a self-filled health questionnaire and a detailed clinical assessment were combined. The aim was to check whether these extended examinations are necessary for a successful recruitment of study participants or whether subjective information on the health status alone is sufficient.

Methods

A total of 469 volunteers (median: 24 (17-57) years, 56% female) completed the health questionnaire. The subsequent clinical assessment included anamnesis, physical examination and an electrocardiogram. The reported smoking status was verified by quantifying cotinine in urine. The allergy status was assessed by skin prick testing to nine ubiquitous allergens and measurement of specific IgE antibodies in blood samples. Additionally, a pulmonary function and a methacholine challenge test were performed to assess respiratory health and bronchial hyperresponsiveness.

Results

Based on the health questionnaire, 100 non-smoking volunteers (median: 24 (18-40) years, 52% female) reporting no respiratory diseases, allergies or chronic illnesses participated in the baseline investigation. Five subjects were excluded due to positive cotinine tests or an atypical electrocardiogram. In eight subjects, obstruction or a bronchial hyperreactivity were diagnosed, and 29 subjects were classified as atopic. Finally, 58 participants fulfilled the inclusion criteria for the studies.

Conclusion

Although young, healthy and non-smoking volunteers participated in the baseline investigation, almost one third showed signs of atopy and 10% even airway disease or bronchial hyperreactivity. This suggests that the investigations seem to be necessary for a successful recruitment of healthy voluntary study participants.