

HOW HEALTHY IS HEALTHY? - COMPARISON BETWEEN SELF-REPORTED SYMPTOMS AND CLINICAL OUTCOMES IN CONNECTION WITH THE ENROLLMENT OF VOLUNTEERS FOR HUMAN EXPOSURE STUDIES ON SENSORY IRRITATION EFFECTS

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

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

Question Controlled human exposure studies on sensory irritation effects are usually performed with healthy volunteers. Therefore, in most studies pre-screening by a health questionnaire and a detailed medical examination are combined. The aim of this report is to proof whether self-reported information about smoking and health status is sufficient or whether additional clinical tests are necessary for a successful and safe enrollment of healthy volunteers.

Methods A total of 409 volunteers (55% female; 17-57 years; 79% non-smoker) completed the health questionnaire. Medical examination included electrocardiogram, blood and urine screening and an olfactory function test. Atopy status was assessed by skin prick (SPT) or specific IgE testing. Lung function and a methacholine challenge test were performed to assess respiratory health and bronchial hyperresponsiveness.

Results In total, only 107 non-smoking volunteers (58% female, 19-40 years) reporting no respiratory diseases, allergies or chronic illnesses could be selected in the detailed medical examination. Eight subjects were excluded due to positive cotinine tests, laboratory test results outside the reference range, or an atypical electrocardiogram. In 12 subjects, obstruction or a bronchial hyperreactivity were diagnosed. Among the remaining 87 healthy subjects 26 were classified as atopic and 2 were diagnosed hyposmic.

Conclusion Although young and non-smoking volunteers considered healthy by questionnaire, 20% showed signs of a heart, liver or airway disease and additional 24% were classified as atopics. This suggests that more detailed clinical testing may be necessary to safely exclude those who may react with an adverse health response to controlled exposure with sensory irritants.