

European Respiratory Society Annual Congress 2012

Abstract Number: 1580

Publication Number: P2956

Abstract Group: 7.4. Paediatric Respiratory Infection and Immunology

Keyword 1: Infections **Keyword 2:** Immunology **Keyword 3:** Children

Title: Modulation effect of beta-glucan isolated from *Pleurotus ostreatus* in children with recurrent respiratory tract infections

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Body: Introduction: Recurrent respiratory tract infections (RRTI) present very frequent problem in pulmonologist praxis. Several natural preparations have been used for their prevention, but only few of them have scientific evidence for a real clinical efficacy. Objectives: The aim of the study was to evaluate the preventive effect of Imunoglukan P4H®, syrup containing imunoglukan – beta-glucan from *Pleurotus ostreatus*, on the frequency of RRTI in children. Methods: In double-blind, placebo-controlled study, 175 children (5.65±2.39 years) with ≥5 respiratory infections in previous 12 months were studied. Children were treated for 6 months with Imunoglukan P4H® or with artificial syrup with vitamin C (placebo group). During three visits questionnaires were fulfilled and immune parameters in blood were evaluated. Results: In active group, 36% of the children did not suffer from any respiratory infection during the treatment compared to 21% in placebo group (p<0.05). Imunoglukan P4H® significantly decreased the frequency of flu and flu-like diseases and also lower respiratory tract infections. 65% of physicians evaluated the effect of Imunoglukan P4H® as excellent (significant decreased morbidity) compared to 39% for placebo (p<0.05). We observed a significant modulation effect of Imunoglukan P4H® on humoral and cellular immunity. Conclusions: Our study provided relevant evidence for preventing effect of Imunoglukan P4H® on the incidence of respiratory infections and revealed its complex immunomodulating activity. This is the first double-blind, placebo-controlled study in children with RRTI aimed on the preventive effect of beta-glucans on respiratory morbidity.