

# Effect of supplementation with beta-glucan from *Pleurotus* ostreatus in children with recurrent respiratory infections

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### **Background and Objectives:**

Recurrent respiratory tract infections (RRTIs) are among the most frequent consultations in paediatric practice, especially in children of preschool age. A variety of nutritional supplements have shown clinical efficacy in the prevention of RRTIs, but only a few of them are supported by scientific evidence. Dietary supplementation with beta-glucans (glucose polymers naturally present in fungi, yeast, bacteria and cereals) has been proposed as a useful resource for the prevention of RRTIs<sup>2</sup> as immunomodulators of natural origin, which activate multiple components of the immune system and thus modulate the immune response. The objective of the study was to evaluate the preventive effect on respiratory infections in children with dietary supplementation with beta-glucan from *Pleurotus ostreatus* over a period of 3 months.

#### **Material and Methods:**

Prospective, observational, multicentre study of patients aged 1 to 10 from 20 paediatric consultations in 3 autonomous communities of Northeastern Spain. Patients with a history of RRTIs in the previous 12 months were included. Patients received 1ml/5kg of Imunoglukan P4H®, a syrup with beta-glucan from *Pleurotus ostreatus* and Vitamin C, during 3 months and were followed up for 6 months after the end of treatment. The number of RTIs, visits to the Emergency Department (ED) and Hospitalizations were registered in four visits during the follow-up period. Such records were compared to the number of events during the same 6 months' period in the previous year (October to March). Data from treatment compliance, acceptability, improvement perceived by parents, satisfaction with the product and adverse events were also registered. Patients were classified into age groups (<3.5 or ≥3.5 yr. old) and according to the number of RTIs (≤6 or > 6 RTIs). Student's t and Wilcoxon tests were used for numerical data and Chi-square tests with Odds Ratios with 95% confidence intervals OR[CI95%] for categorical data. All analyses were done in an ITT basis.

#### Results:

A total of 166 patients with a mean±SD age 3.0±1.7 yr. were analyzed. The number of total RTIs was significantly lower compared to the previous year (4.08±2.25 vs. 8.80±3.41; p<0.001). This trend was also observed when comparing the incidence of RTI regarding age groups: children under 3.5 yr. old (4.44±2.24 vs. 9.45±3.18; p<0.001) and children above 3.5 yr. old (3.26±2.07 vs. 7.30±3.49; p<0.001). (Fig. 1). There was a significant reduction of the incidence of each RTI. The number of otitis was reduced by 50.53% (104 vs. 47; OR: 3.85 [2.34-6.36]), likewise for common cold by 27.03% (198 vs. 98; OR:5.29 [2.66-10.65]), by 44.14% for pharyngitis (123 vs. 62; OR: 4.16 [2.5-6.94]), by 72.78% for laryngitis (53 vs. 13; OR: 4.98 [2.48-10.15]) and by 45.73% in the frequency of bronchitis (111 vs. 54; OR: 3.61 [2.2-5.93]). In cases of pneumonia, a reduction of the frequency was also observed, with 46.7% less patients with this process (25 vs. 12; OR: 2.04 [0.93-4.5]). Nevertheless, this reduction did not reach statistical significance (p=0.055). Regarding RTIs frequency groups, the percentage of patients with ≤ 6 episodes during the study was higher when compared to the previous year (84.83% vs. 54.38%; p<0.001), with a reduced proportion of patients with >6 RTI; p<0.001 (Fig. 2). Other variables such as missing days of school due to a RTI and need for hospitalization did not differ throughout the studied years. In the case of visits to ED, a lower number of patients reported at least once during the study when compared with the previous year (p<0.001). (Fig. 3). An 85.71% of parents scored the improvement of their kids as "better". Product acceptability was scored as "good" or "very good" in 90.6% of cases. (Fig. 4) The security analysis showed a 97% of patients free from any adverse event.

## **Conclusions:**

The use of the nutritional supplement Imunoglukan P4H® was effective in preventing respiratory tract infections in paediatric patients:

- The total number of respiratory infections was significantly reduced to less than half of the infections reported in the same period of the previous year, as well as for the incidence of each RTI.
- •The probability to develop respiratory infections decreased by 3.6 to 5.3 times.
- Parents confirmed the improvement of their children in 85.7% of cases and acceptability was favorably rated in 90.6%.

Figure 1. Mean number of infections

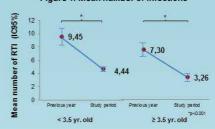


Figure 2. Proportion of patients with >6 RTI

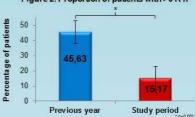


Figure 3. Proportion of patients with at least one visit

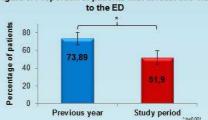


Figure 4. Parents' opinion on improvement and acceptability

