

Effect of oral Broncho-Vaxom® on nasal challenge with grass pollen in patients with allergic rhinitis



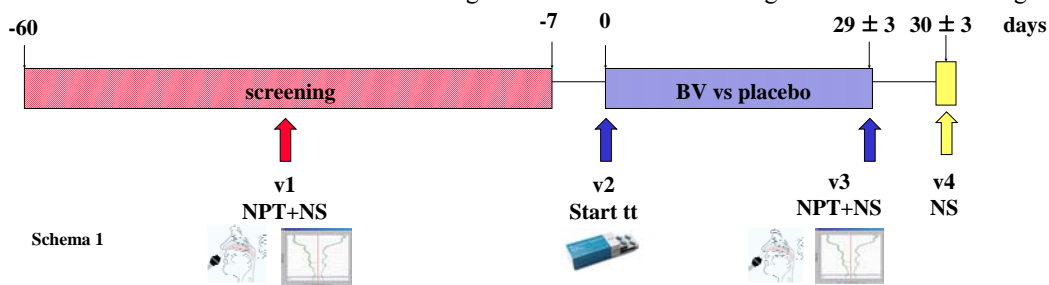
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INTRODUCTION

Oral administration of bacterial extracts (Broncho-Vaxom®, BV) was able to switch a Th2 type immune response towards a Th1 type in animal models suggesting the potential for BV to prevent allergy symptoms. We thus investigated the effect of one-month oral administration of BV on a nasal provocation test (NPT) with grass pollen in adults with allergic rhinitis.

METHODS

- Randomized, placebo-controlled, double-blind parallel-group study
- 60 subjects, age 18-40
- Seasonal allergic rhinitis determined by:
 - positive skin tests and /or specific Ig E for grass pollen
 - nasal reaction threshold $\leq 10^4$ 000 SQs/ml during screening
- Administration of Broncho-Vaxom® vs placebo during 30 days (1capsule/day)
- Nasal provocation test (NPT) at screening and one day before the end of treatment, nasal samples (NS) at visit 1, 3 and 4 (**schema 1**)
- **Endpoint**: difference in combined clinical threshold to allergen NPT of at least one allergen dose level between groups



RESULTS

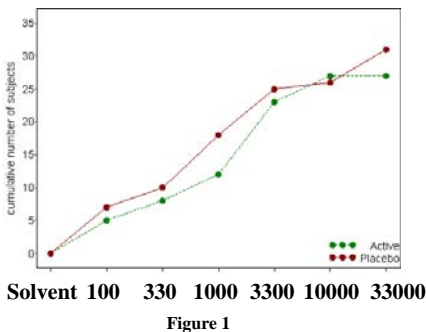


Figure 1

- Median threshold dose level at visit 1 : **1000** SQ in both groups
- Median threshold dose level at visit 3 : **1000** SQ in PL, **3300** SQ in BV group
 → trend toward improved protection provided by BV as compared to placebo
- Nasal secretion, PNIF, MCA, number of sneezes $p < 0.05$
- Nasal pruritus and congestion by VAS $p < 0.05$

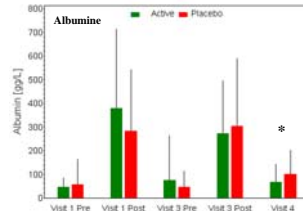


Figure 2

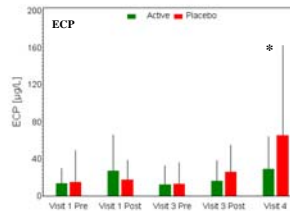


Figure 3

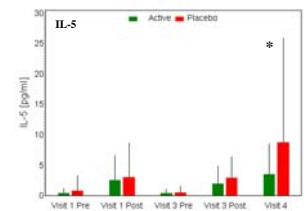


Figure 4

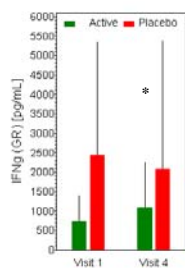


Figure 5

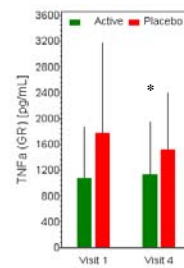


Figure 6

- Albumin, ECP and IL-5 values in nasal samples were significantly lower in the BV group compared to the placebo group (**figures 2, 3 and 4**)
- IFN- γ and TNF- α (**figures 5 and 6**) produced by PBMC in response to grass extract increased significantly in the BV group between visit 1 and visit 4
- All other parameters (eosinophils, IL-8, IL-10 in NS and IL-5, IL-8, IL-10, IL-13, TGF- β in serum) showed no significant differences between the treatment groups in the change between visit 4 and baseline (visit 1)

CONCLUSIONS

- A short term treatment period with BV compared to placebo was able to **downregulate Th2 markers** of the nasal and systemic proinflammatory response in a provocation test with allergen.
- Exudation of albumin, a robust marker of allergic inflammation, into nasal secretion was limited after BV treatment.
- There was a trend toward **improvement of global clinical score** of NPT
- The administration of **BV is simple and safe**
- BV may contribute to **improve established seasonal allergic rhinitis**. Further longer-term seasonal studies are warranted.