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GRASS POLLEN CARBAMYLATED MONOMERIC ALLERGOID ADMINISTERED BY INJECTIVE ROUTE FOR ALLERGIC RHINO-CONJUNCTIVITIS: PRELIMINARY DATA ON SAFETY AND EFFICACY

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Background Monomeric carbamylated allergoids are chemically modified allergens featured by a reduced IgE-binding activity conferring reduced allergenicity, but preserved structural conformation and immunogenicity. Their safety profile, efficacy and tolerability have been extensively documented after sublingual administration. Purpose of this study was to obtain data on the safety and efficacy when these extracts are delivered subcutaneously.

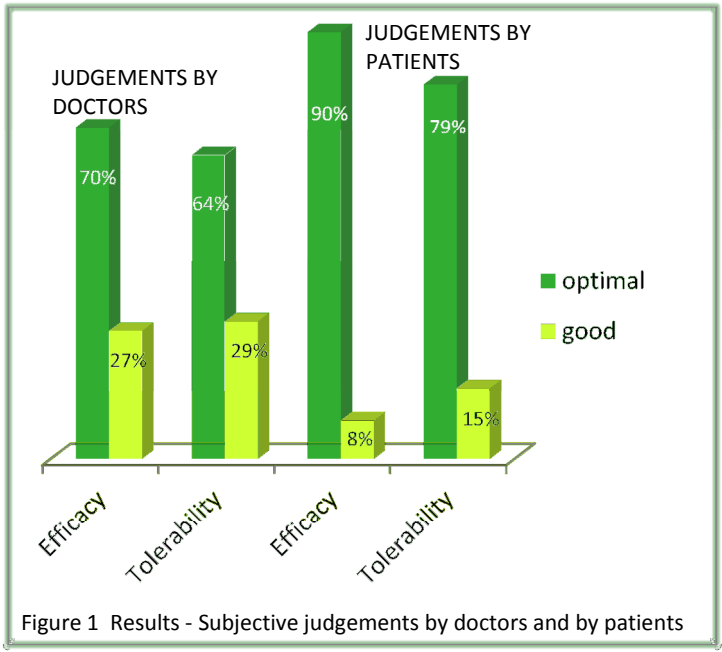

Figure 1 Results - Subjective judgements by doctors and by patients

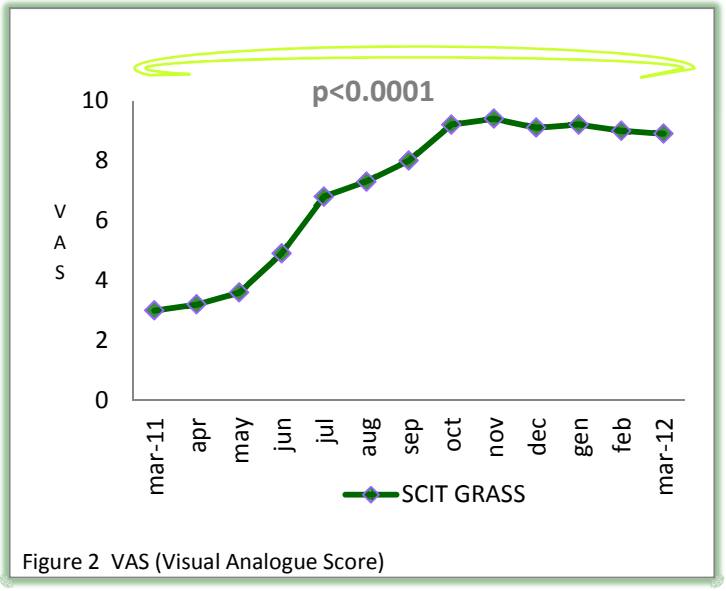

Figure 2 VAS (Visual Analogue Score)

Method Patients 5-70 year-old with moderate to severe allergic rhino-conjunctivitis with/without asthma due to grass pollen and positive skin test mean diameter, were recruited after a run-in spring season to receive, from November 2011 to June 2012, grass carbamylated allergoid with a monthly dose of 0.80 ml, (10 BU equivalent to 5mcg/ml of major allergen), following an induction phase (0.10-0.20-0.40-0.60-0.80 ml with weakly increase). Outcomes were patient's allergic condition self-assessed and evaluated by doctors by means of a visual analogue scale (VAS 0-10), symptomatic drugs consumption (scarce, no more than 5 days with the need of a rescue therapy in that month; moderate, no more than 10 days; elevated, more than 10 days), frequency of adverse reactions.

Results Thirty nine patients mean age 29.6, 44% males, mean disease duration 8.5 years, were treated. Their allergic condition largely improved after 8 months of treatment with a significant mean VAS improvement (+3.3, SE=0.5, p<0.0001) from spring 2011 to spring 2012, consistent with doctors' judgment (mean VAS change +4.05, SE=0.5, p<0.0001). Drugs usage was scarce (less than 5 days a month with the need of antihistamines, nasal corticosteroids or other drugs) during the period. During the build-up phase, 15 adverse reactions overall occurred (12 local and 3 systemic), respectively 3 with 0.1 ml, 2 with 0.2 ml and 0.4 ml, 6 with 0.6 ml, 2 with 0.8 ml. Patients experiencing at least one reaction were 8 (20%). The maintenance phase was well tolerated with no signaled adverse reactions. Non severe reactions occurred.

Conclusions Carbamylated monomeric allergoid of grass pollen appears well tolerated and effective in improving the allergic condition when delivered subcutaneously for 8 months. Rare adverse reactions, mainly local, may occurs during the induction phase in particularly susceptible patients.