SAFETY AND EFFICACY OF CARBAMYLATED MONOMERIC ALLERGOID ADMINISTERD BY SUBCUTANEOUS ROUTE IN A DEPOT FORMULATION

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BACKGROUND

Immunotherapy with monomeric allergoid proved to be well tolerated, safe and effective in patients with respiratory allergy.

VISUAL ANALOGIC SCALE

	BASAL	AFTER ALLERGOID SLIT	P
V.A.S.	2,8±1,6	6,8±2,4	p<0,05

AIM OF THE STUDY

To assess the tolerability of a carbamylated monomeric allergoid given by subcutaneous route to patients with allergic rhinitis with or without asthma due to Dermatophagoides (house dust mite).

METHODS

EFFICACY
Physician's global evaluation

° Very good	2
° Good	10
° Total	12

TOLERABILITY
Physician's global evaluation

° Very good	2
° Good	10
° Total	12

We evaluated, in a prospective open-label phase II study, lasting about 8 months, 15 patients (8M/7F, age: 15 - 45 years, mean age: 30 years), sufferring from allergic rhinitis with (5) or without (10) asthma mainly due to house dust mites. The patients were given subcutaneously, during the first 5 weeks of the study, an increasing dose (0.1, 0.2, 0.4, 0.6 mL at 10,000 BU/mL) of the carbamylated monomeric allergoid (Lofarma S.p.A., Italy) and then, during the 7 maintenance months, a dose of 0.8 mL (at 10,000 BU/mL) with a monthly cadence. The amount of major allergen was 4 µg of group 1 per mL. At each visit, they were evaluated for any local and/or systemic adverse reaction (AR) related to the administration of the product. At baseline and at the end of the study a visual analogue scale (VAS) was performed as well.

RESULTS

No ARs were observed in 7 out of 15 patient (46.6%). Eight patients (53.3%) showed ARs. They were nearly all local and all mild: pain at the arm (2 patients), local itching (3 patients), local reaction of the dimension of a walnut (2 patient) and fever the day after the injection (1 patient). None of these ARs caused either the interruption of the treatment or the hospitalisation of the patient. There was an improvement of VAS score from 2.8 ± 1.6 to 6.8 ± 2.4 ($p<0.05$).

CONCLUSION

The carbamylated monomeric allergoid, given by subcutaneus route, is well tolerated by most of the allergic treated patients and is effective already after 8 months.