Carbamylated Monomeric *Dermatophagoides* Allergoid: A Tolerability Study

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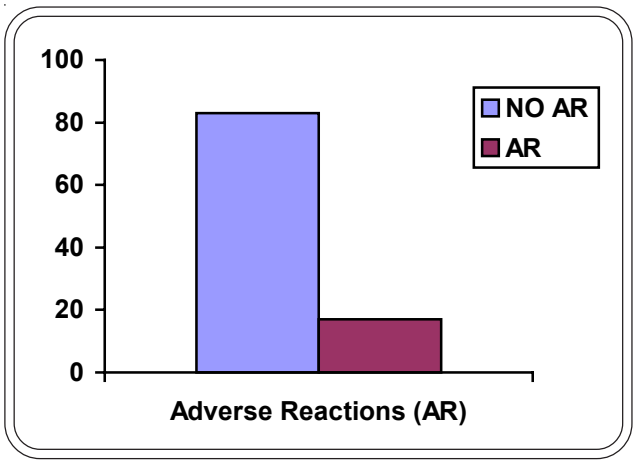
Background: Purpose of this study was to assess the tolerability of a carbamylated monomeric allergoid given both by subcutaneous and sublingual route to patients with allergic rhinitis with or without asthma.

Methods: We evaluated, in a prospective open-label phase II study, lasting 12 weeks of enrolment and 16 weeks of treatment (between October 2007 and April 2008) 45 patients (16M/29F, age: 18-49 years, mean age: 33.6 years), suffering from allergic rhinitis with (21) or without asthma (24) mainly due to house dust mites. The patients were given subcutaneously, during the first 12 weeks of the study, an increasing dose (0.1, 0.3, 0.5, 0.8 mL at 100, 1,000 and 10,000 carbamilated unit per mL [CU/mL]) of the carbamylated monomeric allergoid (Lofarma, Italy) and then, during the first 4 maintenance weeks, a fix dose of 0.8 mL (at 10,000 CU/mL) weekly. The amount of major allergen was 4 µg of group 1 per mL. After this period the monomeric allergoid was administered by sublingual route to all the patients at the same intervals. At each visit, they were evaluated for any local and/or systemic adverse reactions (AR) related to the administration of the product.

Adverse Reaction	Number of patients
Mild dispnoea	1
Episodes of asthma	2
Pain at the arm	1
Diffuse itching	2
Headache	1
Urticaria at the face	1



Results: During the first phase no AR were observed in 37 out of 45 patients (82.3%). Eight patients (17.7%) showed AR. They were: mild dispnoea (1 patient), episodes of asthma (2 patients), pain at the arm (1 patient), diffuse itching (2 patients), headache (1 patient) and urticaria at the face (1 patient). None of these AR caused either the interruption of the treatment or the hospitalisation of the patient. No correlation was found between the dose administered and the occurrence of the AR. No AR was observed when the monomeric allergoid was given by sublingual route.

Conclusions: The carbamylated monomeric allergoid, given both by subcutaneus and sublingual route, is well tolerated by most of the allergic treated patients.