Comparison of three modalities of mucosal administration of carbamylated Title: monomeric allergoid tablets to treat respiratory allergy due to house-dust mites in a real-life setting for three years

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> **Background:** Carbamylated allergoids (monoids) are chemically modified allergens resistant to proteolytic activity of gastroenteric enzymes. Pharmacokinetics studies revealed they exert sublingual tolerogenic mechanisms and some systemic effects after swallowing. Different modalities of mucosal administration were compared to explore the contribution of sublingual and oral absorption.

Method: Adults with respiratory mite-allergy, in addition to daily cetirizine randomly received monoid (1000UA twice/week) for 3 years with 3 intake modalities: sublingual/spit (SSP), oral or sublingual/swallow (SSW). A control group received cetirizine alone. Upper (UAS) and lower (LAS) airways symptoms, on-demand nasal steroids (NS) and salbutamol (B2) were registered with 6-month diary card in winter. Nasal eosinophils (EOS) were compared season by season, bronchial reactivity (MCH), lung function (FEV), and skin sensitizations at the beginning and after 3 years.

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Results: Eighty patients concluded the study. A significant improvement was observed in all outcomes with all modalities in respect to controls. Notably SSW was superior to both oral and SSP in reducing UAS, LAS, NCS, EOS, and improving FEV. Oral was equivalent to SSW in reducing the use of B2; oral was also equivalent to SSP in reducing UAS, LAS, B2, FEV, MCH and superior on NCS and EOS. The MCH threshold increase determined by SPP was inferior to SSW but not to oral. Only SSW appeared protective upon the onset of new sensitizations.

Conclusion: Monoid for 3 years provides additional relief to mite-allergic patients treated with antihistamine. Both sublingual and oral absorption contribute in making sublingual/swallow the most advantageous administration modality.