

Sublingual allergoid immunotherapy with a 4-day updosing phase versus traditional initial scheme, or drugs alone. A controlled, randomised study in rhinitic patients with or without mild allergic asthma.

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Background: Specific immunotherapy with the sublingual monomeric allergoid (allergoid SLIT, Lofarma SpA, Milan, Italy) has shown to be effective, safe and well tolerated in all the clinical studies conducted so far. The updosing phase is, however, rather time consuming and complex. We thus decided to shorten and simplify it using a new initial phase lasting only 4 days verifying, in the meantime, if it was able to maintain the same safety and tolerability profile of the traditional one. Moreover, we investigated the efficacy by comparing the two SLIT regimens versus the drugs alone (controls).

Methods: We evaluated 45 patients (20 male, 25 female, mean age 29.7±12.2 years; range 7-55) with a history of moderate-severe rhinitis with or without mild asthma due to perennial and/or seasonal allergens: house dust mites, grass, cat and dog dander, *Parietaria*, *Olea*, *Cupressus*, *Compositae* and *Alternaria*. The 4-day updosing (with only 1000 AU tablets), was the following: 1° day: ½ tablet; 2° day: ½ tablet + ½ tablet; 3° day: ½ tablet + 1 tablet; 4° day: 1 tablet + 1 tablet. The traditional initial scheme was that reported on the product's instructions leaflet (lasting from 14 days to 14 weeks). During the maintenance therapy all the SLIT patients received 1000 AU/week for 12 months.

Results: Most of the patients tolerated the fast updosing phase but one that showed nausea, gastric pyrosis and dizziness. During the 12-month maintenance therapy, patients' symptoms, measured by VAS, improved consistently in both the SLIT groups in comparison to controls (p<0.001). Rescue medication consumption was reduced in the two active groups more than in the controls. One case of recurrent epistaxis was observed during this phase.

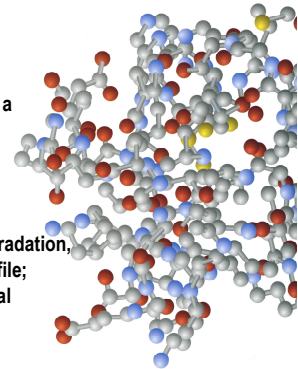
Conclusions: The allergoid SLIT, even if started through an updosing of only 4 days (beginning directly with the dose of 500 UA), proved to be safe, well tolerated and effective already after 12-month treatment.

Monomeric Allergoid

SubLingualImmunoTherapy

The active principle, a monomeric allergoid obtained by a chemical modification of allergens, has three main advantages over the native allergens:

It prevents side-effects; Being able to evade enzymatic degradation, it has a superior bioavailability profile; Thanks to a molecular size identical to its natural counterpart, it can be absorbed by oromucosal way with optimal pharmacokinetics.



Allergoid SLIT in tablets A simple treatment schedule

INDUCTION

1 st day	2 nd day	3 rd day	4 th day
½ tablet	1 tablet	1½ tablet	2 tablets

TREATMENT

Cumulative dose of 52000 AU:
1 tablet a week x 52 weeks