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A polycentric, randomized, parallel-group, study on Lertal®, a multicomponent nutraceutical, as preventive treatment in children with allergic rhinoconjunctivitis: phase II

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Abstract

Background: Lertal®, an oral nutraceutical, contains extract of Perilla, quercetin, and Vitamin D3. The current polycentric, randomized, parallel-group, controlled study aimed in the Phase II to evaluate the efficacy and safety of Lertal® in preventing allergic rhinitis (AR) exacerbations in children after the end of the pharmacological treatment phase.

Materials and methods: One hundred twenty-eight children completed Phase II. Sixty-four children continued Lertal® treatment (Lertal® Group: LG) and 64 ones did not assume any medication (Observation Group: OG) for 4-12 weeks. The study endpoints were the number, intensity, and duration of AR exacerbations, and the length of symptom-free time.

Results: Children of LG halved the risk (HR = 0.54) of having AR exacerbation. Children of LG had significantly ($p = 0.039$) less AR exacerbations than OG children. In children with AR exacerbations, the total number of days in which each patient took at least one rescue medication was significantly ($p = 0.018$) lesser in LG children than OG ones. In the global population, the cumulative days treated with rescue medication was significantly ($p < 0.0001$) higher in OG than in LG. There was no clinically relevant adverse event.

Conclusions: The present study documented that prolonged Lertal® assumption was safe and able to significantly reduce, such as halving, the risk of AR exacerbation, their duration and the use of rescue medications, after the suspension of the one-month antihistamine treatment. Therefore, Lertal® could be envisaged as an effective preventive treatment in AR children able to guarantee long symptom-free time.