

# A polycentric, randomized, double blind, parallel-group, placebo-controlled study on Lertal<sup>®</sup>, a multicomponent nutraceutical, as add-on treatment in children with allergic rhinoconjunctivitis: phase I during active treatment

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## Abstract

Allergic rhinoconjunctivitis (AR) treatment is usually pharmacological in children, but medications are merely symptomatic, may not be completely effective, and may have relevant side effects. Thus, doctors and parents look at complementary medicine, including nutraceuticals. Lertal<sup>®</sup>, an oral nutraceutical, contains extract of *Perilla*, quercetin, and Vitamin D3. It has been reported that adults with AR diminished allergic symptoms and medication use during Lertal<sup>®</sup> therapy. Therefore, the current polycentric, randomized, double blind, parallel-group, placebo-controlled study aimed to evaluate the efficacy and safety of Lertal<sup>®</sup> as an add-on treatment in children with AR. In this study, 146 children (94 males and 52 females, mean age  $9.1 \pm 1.88$ ) were randomly assigned to Lertal<sup>®</sup> + standard treatment or Placebo + standard treatment and were visited at baseline (W0), and after 2 (W2) and 4 weeks (W4). Standard treatment consisted of continuous antihistaminic schedule. The primary endpoint was the Total Symptom Score (TSS - last 12 hours) change from the baseline to the end of the 4-week treatment. Both groups significantly ( $p < 0.0001$  for both) reduced TSS (last 12 hours) after 4 weeks (% change: - 63.6% in Lertal<sup>®</sup>-group and - 60.7% in Placebo-group;  $p = n.s.$  intergroup analysis). Notably, 24 children had symptom worsening between W2 and W4: 8 in the Lertal<sup>®</sup>-group and 16 in the Placebo-group, with significant intergroup difference ( $p < 0.05$ ). All of them were poly-allergic subjects exposed to multiple allergens. There was no relevant adverse event. The present study documented that Lertal<sup>®</sup>, as add-on treatment, was able to significantly prevent the occurrence of clinical worsening and was safe in AR poly-allergic children.

**Keywords:** *Perilla frutescens*; add-on treatment; allergic rhinoconjunctivitis; nutraceutical; quercetin; vitamin D3.