Epicutaneous Immunotherapy (EPIT) is effective and safe to treat Peanut Allergy: a multi-national double-blind placebo-controlled randomized phase IIb trial.


Rationale: To date there is no specific approved treatment for peanut allergy. EPIT is well tolerated and appears promising for the treatment of peanut allergy.

Methods: In a multicenter double-blind, placebo-controlled phase IIb trial, 221 subjects (6 – 55 years) reacting at a peanut protein (pp) eliciting-dose (ED) ≤300mg during DBPCFC were randomized to 1 year Viaskin® Peanut (VP), at different doses (50μg, 100μg, 250μg pp), or Viaskin® placebo. The primary efficacy endpoint at 1 year was the proportion of responders with a pp ED 10-fold greater than the pp ED at entry or achieving a post-treatment ED ≥1000mg. Cumulative reacting dose (CRD) of pp was also measured. Immunologic studies were performed at entry, 3, 6 and 12 months.

Results: The overall primary efficacy endpoint was met, with VP250 showing best results: 50.0% responders vs 25.0% with placebo, p=0.0108; children (6-11 years) exhibited 53.6% responders vs 19.4% for placebo, p=0.0076. In children, the mean CRD showed a VP dose-dependent response: +61mg, +471mg, +570mg and +1121mg for placebo, VP50, VP100 and VP250 respectively. Children’s immunological responses were robust: with VP250 - PN-IgE exhibited a median increase ≥50 kUA/L at 3 months and decreased back to baseline at 12 months; median PN-IgG4 at 12 months increased in a dose-dependent fashion: 5.5-, 7.2- and 19.1-fold for VP50, VP100 and VP250 respectively. Compliance was >95%, dropout for adverse events <1%, and there were no serious adverse events related to treatment.

Conclusion: In peanut allergy, EPIT appears safe and effective; the CRD was dose-dependent and maximum efficacy was seen with VP250.
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