REAL-LIFE SAFETY STUDY WITH A HOUSE DUST MITE-POLYMERIZED EXTRACT IN PEDIATRIC PATIENTS

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BACKGROUND

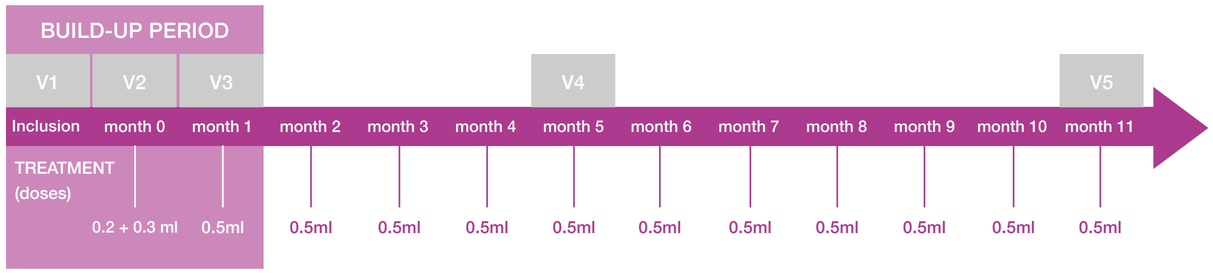
The evidence for efficacy and safety of house dust mites (HDM) allergoids in pediatric allergic patients is limited, particularly in children younger than five years of age.

METHODS

In this multicenter, prospective, non- interventional study, children with HDM allergy received a subcutaneous immunotherapy of *D. farinae* and *D. pteronyssinus* (1:1) according to a rush schedule. They had a positive prick test to *D. farinae* and/or *D. pteronyssinus* and an allergen specific serum IgE level ≥3.5 kU/L. The study was approved by a clinical research ethics committee (Teknon Medical Center, Barcelona).

Objective: To assess the safety and effectiveness of a HDM allergoid (Probelte Pharma) administered to children between 3 and 11 years old under clinical routine conditions for one year.

Figure 1. Study timeline



Primary endpoint: The number of local and systemic adverse reactions according to the WAO SCIT grading system. Preliminary safety data from the build-up period (0.2 + 0.3 ml with an interval between doses of 30 minutes followed by 0.5 ml at day 28) are reported.

RESULTS

97 patients were enrolled in the study and 87 finalized the build-up period. The number of adverse reactions was 9 in 261 doses administered (3.4%). All of them occurred in the group of age 6-11 years. One patient (1.1%) presented a delayed systemic reaction grade I (rhinorrhea, sneezing, nasal and ocular pruritus) that resolved with an antihistaminic treatment. No patient withdrew treatment.

Population Characteristics (N= 97)

Mean age (y.o.): 8,5
Range 3-5 y.o.: 14.6%
Range 6-11 y.o.: 85.4%

Diagnosis:
Rhinitis/ rhinoconjunctivitis + asthma: 74%
Rhinitis/rhinoconjunctivitis: 25%
Asthma: 1%

Safety Results (N=87)

9 adverse reactions (AR):
- 8 local reactions (5 < 5cm and 3 > 5cm)
- 1 systemic grade I reaction
(rhinorrhea, sneezing, nasal and ocular pruritus)

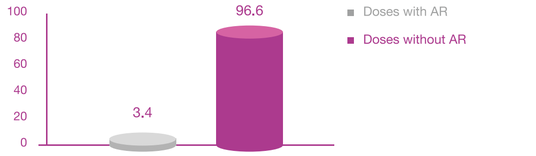


Figure 2. Adverse reactions per dose administered (%)

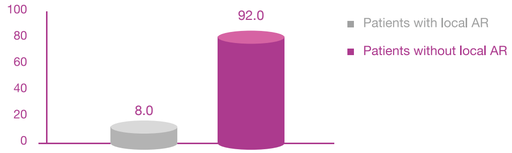


Figure 3. Patients with local adverse reactions (%)

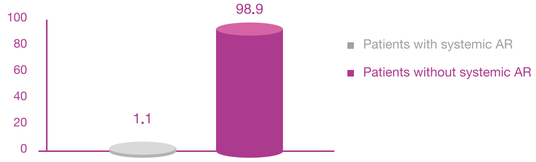


Figure 4. Patients with systemic adverse reactions (%)

CONCLUSION

Current data support that this HDM allergoid is safe in children from 3 to 11 years old when administered under routine clinical conditions. ClinicalTrials.gov Identifier: NCT03963947.