

Fel d 1-derived synthetic peptide immuno-regulatory epitopes show a long-term treatment effect in cat allergic subjects.

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Abstract

BACKGROUND:

Cat-PAD, the first in a new class of synthetic peptide immuno-regulatory epitopes (SPIREs), was shown to significantly improve rhinoconjunctivitis symptoms in subjects with cat allergy up to 1 year after the start of a short course of treatment.

OBJECTIVE:

To evaluate the long-term effects of Cat-PAD on rhinoconjunctivitis symptoms following standardized allergen challenge 2 years after treatment.

METHODS:

In a randomized, double-blind, placebo-controlled, parallel group study, subjects were exposed to cat allergen in an environmental exposure chamber (EEC) before and after treatment with two regimens of Cat-PAD (either eight doses of 3 nmol or four doses of 6 nmol) given intradermally over a 3-month period. In this follow-up study, changes from baseline in rhinoconjunctivitis symptoms were reassessed 2 years after the start of treatment.

RESULTS:

The primary endpoint showed a mean reduction in total rhinoconjunctivitis symptom scores of 3.85 units in the 4 × 6 nmol Cat-PAD group compared to placebo 2 years after the start of treatment ($P = 0.13$), and this difference was statistically significant in the secondary endpoint at the end of day 4 when the cumulative allergen challenge was greatest ($P = 0.02$). Consistent reductions in nasal symptoms of between 2 and 3 units were observed for 4 × 6 nmol Cat-PAD compared to placebo between the 2 and 3 h time points on days 1-4 of EEC challenge at 2 years ($P < 0.05$). The 8 × 3 nmol dose did not show a meaningful effect in this study.

CONCLUSION AND CLINICAL RELEVANCE:

A persistent, clinically meaningful reduction in rhinoconjunctivitis symptoms was observed on EEC challenge 2 years after the start of a short course of treatment with 4 × 6 nmol Cat-PAD. This study is the first to provide evidence of a long-term therapeutic effect with this new class of SPIREs.