Safety and efficacy of pimecrolimus in atopic dermatitis: a 5-year randomized trial.

Atopic dermatitis (AD) primarily affects infants and young children. Although topical corticosteroids (TCSs) are often prescribed, noncorticosteroid treatments are needed because compliance with TCSs is poor due to concerns about their side effects. In this longest and largest intervention study ever conducted in infants with mild-to-moderate AD, pimecrolimus 1% cream (PIM) was compared with TCSs. A total of 2418 infants were enrolled in this 5-year open-label study. Infants were randomized to PIM (n = 1205; with short-term TCSs for disease flares) or TCSs (n = 1213). The primary objective was to compare safety; the secondary objective was to document PIM's long-term efficacy. Treatment success was defined as an Investigator's Global Assessment score of 0 (clear) or 1 (almost clear). Both PIM and TCSs had a rapid onset of action with >50% of patients achieving treatment success by week 3. After 5 years, >85% and 95% of patients in each group achieved overall and facial treatment success, respectively. The PIM group required substantially fewer steroid days than the TCS group (7 vs 178). The profile and frequency of adverse events was similar in the 2 groups; in both groups, there was no evidence for impairment.
of humoral or cellular immunity. Long-term management of mild-to-moderate AD in infants with PIM or TCSs was safe without any effect on the immune system. PIM was steroid-sparing. The data suggest PIM had similar efficacy to TCS and support the use of PIM as a first-line treatment of mild-to-moderate AD in infants and children.