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Randomized double-blind placebo-controlled clinical trial to evaluate the effect of a mixture of probiotic strains on symptom severity and use of corticosteroids in children and adolescents with atopic dermatitis

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Resumen del artículo

Abstract

Background: The intestinal microbiota is altered in patients with atopic dermatitis (AD) when compared with those of the healthy population. Some interventions with specific probiotic preparations already demonstrate a change in composition of this microbiota accompanied by improvement in the disease.

Objectives: This research work was designed to evaluate clinical efficacy of the probiotic preparation, and to measure the effect of the intervention on the total dose of corticosteroids administered to subjects.

Methods: This double-blind, randomized, placebo-controlled clinical trial including 70 participants with AD aged 4-17 years was designed to evaluate the clinical effect, compared with placebo, of a probiotic mixture of Bifidobacterium lactis, Bifidobacterium longum and Lactobacillus casei at a total daily consumption of 1 × 109 colony-forming units per capsule, over 12 weeks. After randomization and exclusion, 35 patients were allocated to probiotic and 35 to placebo. Clinical variables analysed were SCORAD (SCORing of Atopic Dermatitis) and Investigator Global Assessment (IGA) indices; effect on the amount of topical corticosteroids used; and assessment of safety.

Results: Mean SCORAD index at 12 weeks showed a statistically significant difference of -5.43 (95% confidence interval -10.65 to -0.21) between probiotic (SCORAD 13.52) and placebo groups (SCORAD 18.96); P = 0.04. Comparison

between groups showed a statistically significant difference in the number of patients with IGA score improvement over the 12-week intervention: 29 of 32 (90.5%) in the probiotic group vs. 17 of 30 (56.7%) in the placebo group ($P < 0.002$). A comparison between groups of the proportions of days using corticosteroids and the total dose (g) of corticosteroids between baseline and end of study showed no significant difference, but between weeks 6 and 12 there was a statistically significant reduction in the probiotic group when compared with the placebo group in both variables. Numbers of adverse events were similar in both groups of treatment.

Conclusions: The probiotic mix used in this clinical trial demonstrated efficacy on the change in activity index of AD compared with placebo. Furthermore, the total number of days and total amount of topical corticosteroids required by participants in the probiotic group showed a significant reduction compared with placebo between 6 and 12 weeks.