

Preliminary pediatric clinical evaluation of the oral probiotic *Streptococcus salivarius* K12 in preventing recurrent pharyngitis and/or tonsillitis caused by *Streptococcus pyogenes* and recurrent acute otitis media.

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Abstract

Background: The oral probiotic *Streptococcus salivarius* K12 has been shown clearly to antagonize the growth of *Streptococcus pyogenes*, the most important bacterial cause of pharyngeal infections in humans, by releasing two bacteriocins named salivaricin A2 and salivaricin B. Unpublished observations indicate that it can also antagonize the growth of other bacteria involved in acute otitis media. Because of its ability to colonize the oral cavity and its safety profile, we have tested its efficacy in reducing the incidence of streptococcal pharyngitis and/or tonsillitis and episodes of acute otitis media.

Methods: We enrolled 82 children, including 65 with and 17 without a recent diagnosis of recurrent oral streptococcal pathology. Of those with recurrent pathology, 45 were treated daily for 90 days with an oral slow-release tablet containing five billion colony forming units of *S. salivarius* K12 (Bactoblis®), and the remaining 20 served as an untreated control group. The 17 children without a recent diagnosis of recurrent oral pathology were used as an additional control group. After 90 days of treatment, a 6month follow-up period without treatment was included to evaluate a possible persistent protective role for the previously administered product.

Results: The 41 children who completed the 90day course of Bactoblis showed a reduction in their episodes of streptococcal pharyngeal infection (about 90%) and/or acute otitis media (about 40%), calculated by comparing infection rates in the previous year. The 90day treatment also reduced the reported incidence of pharyngeal and ear infections by about 65% in the 6month follow-up period during which the product was not administered. Subjects tolerated the product well, with no side effects or dropouts reported.

Conclusion: Prophylactic administration of *S. salivarius* K12 to children with a history of recurrent oral streptococcal pathology reduced episodes of streptococcal pharyngeal infections and/or tonsillitis as well as episodes of acute otitis media.

Keywords: BLIS K12; Bactoblis®; *Streptococcus salivarius* K12; acute otitis media; bacteriocinlike inhibitory substance K12; pharyngitis; tonsillitis

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