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Evaluation of safety and human tolerance of the oral probiotic Streptococcus salivarius K12: a randomized, placebo-controlled, double-blind study.

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Abstract

Streptococcus salivarius is naturally a predominant member of the **human** oropharynx and the commercial **probiotic** strain **K12** has been consumed for more than a decade. The present **study** examines the health responses of **human** volunteers to **oral** ingestion of high doses of S. **salivarius K12**. A **randomized** group of 53 subjects received a dose of 1 × 10(10)cfu S. **salivarius K12** (N=25) or placebo (N=28) for 28 days, followed by a 28-day wash out period. Blood, urine and saliva samples were collected at baseline and following treatment and analyzed, while the **oral** and gastrointestinal **tolerance** of the subjects to the dosing regimen was determined by use of questionnaires. Adverse events (AE)s were recorded for both groups. No statistically significant differences between the **probiotic** and placebo treated groups were detected in either the blood clinical chemistry or hematology results (P>0.05). The questionnaire responses of the subjects indicated that both treatments were well tolerated. The frequency and intensity of AEs was similar in the two groups. This data demonstrates that the daily ingestion of S. **salivarius K12** over a 28-day period does not adversely affect the **human** host and supports the **safety** of its **oral** delivery in a food-based carrier.

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