AMERICAN ACADEMY OF FAMILY PHYSICIANS FOUNDATION

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Efficacy of Saccharomyces boulardii Probiotic in the Prevention of Antibiotic-Associated Diarrhea: A Double Blind Randomized Placebo-Controlled Clinical Trial (G1302)

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Abstract

Family physicians often treat patients with antibiotic-associated diarrhea (AAD), a condition estimated to occur in over 30% of patients seen for diarrhea in outpatient settings. AAD symptoms range from mild to severe, the latter including pseudomembranous colitis with possible bowel perforation and toxic megacolon. While longstanding effort has focused on the effective treatment of AAD, increasing attention is now being paid to its prevention. It is not uncommon for family physicians to recommend probiotics when they prescribe antibiotics such as clindamycin, quinolones, cephalosporins and erythromycin. A commonly recommended and widely distributed probiotic is *Saccharomyces boulardii,* a non-pathogenic yeast found naturally on the skin of lychee and mangosteen fruits. Most research on probiotic use in this country has focused on *Lactobacillus* strains, with relatively few clinical trials on the efficacy of *S. boulardii*. Even fewer studies have Joint Grant Award Application–4 Updated September 2011 investigated the efficacy of *S. boulardii* in a particularly high risk population, namely hospitalized patients receiving IV antibiotics. To develop evidence-based standards of practice for probiotic use, it is important to have rigorous clinical trials that serve as the foundation for these guidelines. The proposed pilot study hypothesizes that hospitalized patients receiving IV antibiotics who take a 21-day course of the *S. boulardii* probiotic will have less AAD, gastrointestinal pain and cramping, bloating and nausea than their counterparts who take a placebo. A longitudinal two-arm double-blind randomized clinical trial will be conducted using a sample of 110 patients randomly assigned to either the *S. boulardii* probiotic or placebo group. Outcome data (AAD, gastrointestinal pain and cramping, bloating and nausea) will be obtained from a

Daily Stool Log completed by subjects and two telephone follow-up interviews conducted by the physician investigators. The study hypotheses will be tested using logistic and multiple regression analyses. This study will provide pilot data for the development of a grant proposal that seeks funding to conduct a larger study focusing on one type of AAD, namely that caused by *Clostridium difficile*.