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Efficacy of an encapsulated probiotic *Bifidobacterium infantis* 35624 in women with irritable bowel syndrome.

Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM.

BACKGROUND: Probiotic bacteria exhibit a variety of properties, including immunomodulatory activity, which are unique to a particular strain. Thus, not all species will necessarily have the same therapeutic potential in a particular condition. We have preliminary evidence that *Bifidobacterium infantis* 35624 may have utility in irritable bowel syndrome (IBS). **OBJECTIVES:** This study was designed to confirm the efficacy of the probiotic bacteria *B. infantis* 35624 in a large-scale, multicenter, clinical trial of women with IBS. A second objective of the study was to determine the optimal dosage of probiotic for administration in an encapsulated formulation. **METHODS:** After a 2-wk baseline, 362 primary care IBS patients, with any bowel habit subtype, were randomized to either placebo or freeze-dried, encapsulated *B. infantis* at a dose of 1×10^6 , 1×10^8 , or 1×10^{10} , cfu/mL for 4 wk. IBS symptoms were monitored daily and scored on a 6-point Likert scale with the primary outcome variable being abdominal pain or discomfort. A composite symptom score, the subject's global assessment of IBS symptom relief, and measures of quality of life (using the IBS-QOL instrument) were also recorded. **RESULTS:** *B. infantis* 35624 at a dose of 1×10^8 cfu was significantly superior to placebo and all other bifidobacterium doses for the primary efficacy variable of abdominal pain as well as the composite score and scores for bloating, bowel dysfunction, incomplete evacuation, straining, and the passage of gas at the end of the 4-wk study. The improvement in global symptom assessment exceeded placebo by more than 20% ($p < 0.02$). Two other doses of probiotic (1×10^6 and 1×10^{10}) were not significantly different from placebo; of these, the 1×10^{10} dose was associated with significant formulation problems. No significant adverse events were recorded. **CONCLUSIONS:** *B. infantis* 35624 is a probiotic that specifically relieves many of the symptoms of IBS. At a dosage level of 1×10^8 cfu, it can be delivered by a capsule making it stable, convenient to administer, and amenable to widespread use. The lack of benefits observed with the other dosage levels of the probiotic highlight the need for clinical data in the final dosage form and dose of probiotic before these products should be used in practice.

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Lactobacillus and bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles.

O'Mahony L, McCarthy J, Kelly P, Hurley G, Luo F, Chen K, O'Sullivan GC, Kiely B, Collins JK, Shanahan F, Quigley EM.

BACKGROUND & AIMS: The aim of this study was to compare the response of symptoms and cytokine ratios in irritable bowel syndrome (IBS) with ingestion of probiotic preparations containing a lactobacillus or bifidobacterium strain. **METHODS:** Seventy-seven subjects with IBS were randomized to receive either *Lactobacillus salivarius* UCC4331 or *Bifidobacterium infantis* 35624, each in a dose of 1×10^{10} live bacterial cells in a malted milk drink, or the malted milk drink alone as placebo for 8 weeks. The cardinal symptoms of IBS were recorded on a daily basis and assessed each week. Quality of life assessment, stool microbiologic studies, and blood sampling for estimation of peripheral blood mononuclear cell release of the cytokines interleukin (IL)-10 and IL-12 were performed at the beginning and at the end of the treatment phase. **RESULTS:** For all symptoms, with the exception of bowel movement frequency and consistency, those randomized to *B. infantis* 35624 experienced a greater reduction in symptom scores; composite and individual scores for abdominal pain/discomfort, bloating/distention, and bowel movement difficulty were significantly lower than for placebo for those randomized to *B. infantis* 35624 for most weeks of the treatment phase. At baseline, patients with IBS demonstrated an abnormal IL-10/IL-12 ratio, indicative of a proinflammatory, Th-1 state. This ratio was normalized by *B. infantis* 35624 feeding alone. **CONCLUSIONS:** *B. infantis* 35624 alleviates symptoms in IBS; this symptomatic response was associated with normalization of the ratio of an anti-inflammatory to a proinflammatory cytokine, suggesting an immune-modulating role for this organism, in this disorder.