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Am J Gastroenterol. 2006 Jul;101(7):1581-90.

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

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Abstract

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 to 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.