ProDURA® Clinical Evidence

Indian Journal of Microbiology.
Sudha, Ratna M, KA Yelikar, S Deshpande. Clinical Study of *Bacillus coagulans* Unique IS-2 (ATCC PTA-11748) in the Treatment of Patients with Bacterial Vaginosis. 2012: Sep; 52(3):396–9.

Topic	What effect does giving the probiotic *Bacillus coagulans* (ProDURA) have on the treatment of bacterial vaginosis?
Background	Bacterial vaginosis is considered to be the most prevalent vaginal infection worldwide. It is characterized by a reduction in the native levels of the good vaginal flora lactobacilli. Antimicrobial therapy used in the disease treatment is often found to be ineffective in eliminating the infection. The spore-forming probiotic *Bacillus coagulans* Unique IS-2 (also known as ProDURA, Unique Biotech Limited, India) is a potential augmentative therapy to standard antimicrobial treatment and may improve the cure rate.
Study Type	Human intervention, unblinded, placebo, control study.
Study Design	In the study, 40 Indian women were diagnosed with bacterial vaginosis by symptoms that included white discharge, pH greater than 4.7, burning micturition, itching, soreness, and redness in the vulva area. The subjects were divided into 2 groups, 20 who used the *Bacillus coagulans* probiotic and an antibiotic, and 20 in the control who used only the antibiotic. The average age of the control group was 33 ± 3 years, and the average age of the probiotic group was 32.5 ± 3 years. A history of previous vaginosis was found in the control group at a rate of 75%, or 15 out of 20 subjects, and in the probiotic group also at a rate of 75%, or 15 out of 20 subjects. The severity of current vaginosis infection (burning micturition and itching) was 35% in each group. Probiotic group subjects were assigned to receive a dose of the antibiotic therapy ofloxacin – Ornidazole – at a strength of 200–500 mg per capsule per day for 5 days along with vaginal pessaries (co-kimaxazol) for 3 days and simultaneously received 2 probiotic capsules containing 1×10^9 CFUs of Bacillus coagulans Unique IS-2 per capsule (ProDURA). The control group received only the same antibiotic therapy.
Subjects	40 Indian women with bacterial vaginosis.
Dosage	2 capsules containing 1×10^9 organisms in each capsule.
Results	At the end of the treatment, 80% of the probiotic group subjects showed a significant positive response as a reduction of vaginosis symptoms compared with only 45% in the control group.
Conclusion	The results of the present study show that the probiotic *Bacillus coagulans* Unique IS-2 (ProDURA) can provide benefits to women being administered antibiotics for the treatment of bacterial vaginosis.

International Journal of Probiotics and Prebiotics.
Sudha, Ratna M, N Radkar, A Maurya. Effect Of Supplementation Of Probiotic *Bacillus coagulans* (ATCC PTA-11748) on Hypercholesterolemia Subjects: A Clinical Study. May 2011;6(2).

Topic	What effect does the supplementation of the probiotic *Bacillus coagulans* (ATCC PTA-11748) have on subjects with hypercholesterolemia?
Background	There is a lack of clinical trials that have background on the cholesterol-lowering effect of probiotics such as *Lactobacillus acidophilus*. *Bacillus coagulans* (formerly known as *Lactobacillus sporogenes*) has been reported to have a hypocholesterolemic effect along with other therapeutic benefits. This current study investigated whether the probiotic *Bacillus coagulans* Unique IS-2 given in capsule form would modify the serum cholesterol levels in hypercholesterolemic subjects for a 60-day period.
Study Type	Human intervention, open-label, single center, phase II clinical study.
Study Design	Thirty hyperlipidemic subjects with serum cholesterol levels greater than 200 mg/dL were divided into 3 groups of 10 subjects each. Two of the groups were designated to receive a daily dose of 2 capsules of probiotic *Bacillus coagulans* Unique IS2 (10 billion CFUs/capsule (Group A) and 20 billion CFUs/capsule (Group B)), while a third group of subjects received standard medication. Serum lipid profiles were tested at days 0, 30, and 60 of the study period.
Subjects	30 patients (15 male and 15 female patients) of either sex ages 30 and older diagnosed with hyperlipidemia (i.e., serum cholesterol levels between 200 and 240 mg/dL).
Dosage	*Bacillus coagulans* Unique IS2 (10 billion CFUs/capsule (Group A) and 20 billion CFUs/capsule (Group B)).
Results	At the end of the study, there were slight reductions in total cholesterol of 11% and LDL of 0.8%, and an increase in the good HDL cholesterol levels of 3.6%.
Conclusion	The results of this study support the theory that the probiotic *Bacillus coagulans* Unique IS-2 (ProDURA) is able to lower total cholesterol and raise the good cholesterol, which improves the HDL-to-LDL ratio lipid profile in people with hyperlipidemia.