

## The effect of probiotic Bacillus coagulans Unique IS-2 vs. placebo on the symptoms management of irritable bowel syndrome in adults

Madempudi RS, Ahire JJ, Neelamraju J, Tripathi A, Nanal S. Randomized clinical trial: the effect of probiotic Bacillus coagulans Unique IS2 vs. placebo on the symptoms management of irritable bowel syndrome in adults. Scientific reports. 2019 Aug 21;9(1):1-9.

## Summary:

The therapeutic effects of B. coagulans Unique IS2 have been well established in children with irritable bowel syndrome (IBS), but its efficacy in adults remain under reported. Thus, in this study the efficacy of B. coagulans Unique IS2 in the management of IBS symptoms in adults was investigated. Patients (n = 153) fulfilling Rome III criteria were provided placebo capsules for a 2 weeks run-in period. Only patients satisfying compliance criteria (n=136) were randomized (double blind) to receive either B. coagulans Unique IS2 (2 billion CFU) or placebo capsules daily for 8 weeks. Reduction of abdominal discomfort/pain intensity and increase in complete spontaneous bowel movements were analyzed as primary end points. Other clinical symptoms of IBS and serum cytokines were also evaluated. B. coagulans Unique IS2 showed significant improvement in primary and secondary endpoints, as compared to placebo. Haematology of both the arms remained normal. No significant changes in pro- (IL-6, IL-12, TNF- $\alpha$ , INF- y) and anti-inflammatory cytokine (IL-10) levels were detected at the end of B. coagulans treatment (8 weeks) as compared to placebo. B. coagulans was well tolerated with no severe adverse events to report. Overall, the results demonstrate that B. coagulans Unique IS2 is efficacious in the management of IBS symptoms in adults (18-60 years).