



Efficacy of *Bacillus coagulans* Strain Unique IS-2 in the Treatment of Patients with Acute Diarrhea

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Summary:

The objective of this study was to evaluate the efficacy and safety of *Bacillus coagulans* strain Unique IS-2 in the treatment of patients with acute diarrhea. To this end, a total of 28 patients with acute diarrhea were included in a prospective, phase II clinical study upon obtaining consent and ethical committee approval. The trial was performed on patients of both sexes between 18 to 55 years of age and having > 3 loose motions in last 24 hours for less than 7 days. All patients were assigned to receive capsule (containing 2 billion CFU of *Bacillus coagulans* strain Unique IS-2) two 6 times daily for a duration of 10 days. Efficacy was evaluated by assessment of duration of diarrhea (in minutes) frequency of defecation (times per day), abdominal pain (3=severe; 2=moderate; 1=mild; 0=absent) and consistency of stool (1=normal, 2=hard, 3=semi liquid, and 4=loose). Safety aspects of capsule were evaluated by assessment of incidence, type of adverse events, physical examination, and clinical laboratory test values (CBC, SGPT, serum creatinine, stool routine and microscopy). Concomitant medications including rescue medications were monitored throughout the study. Efficacy assessment for duration of diarrhea, frequency of defecation, abdominal pain, consistency of stool and fever was done on 1, 3, 6 and 10 days. Mean values for, duration of diarrhea decreased from 35.60 ± 5.46 to 3.52 ± 2.69 min per day, frequency of defecation was decreased from 7.96 ± 3.89 to 0.76 ± 0.60 times per day, abdominal pain decreased from 3.16 ± 0.99 to 0.36 ± 0.49 and consistency of stool improved from -3.84 ± 0.55 to 1.00 ± 0.00 . No significant change in safety parameters was observed during treatment. This trial demonstrates that utilization of *B. coagulans* Unique IS-2 strain is efficient and safe to treat the patients with acute diarrhea.
