

Objective: To observe the health benefits and safety of orally administered SB-300 in HIV+ subjects with chronic diarrhea.

Methods: This is an open label pilot study. HIV+ subjects with history of chronic diarrhea defined as >3 abnormal (i.e., soft or watery) stools per day for at least 14 days preceding the study initiation. Subjects discontinued all antidiarrheal agents 24 hours prior to enrollment. Each subject received SB-300 and was instructed to take 2 tablets (700mg) every 6 hours for a 2 week period. They also were asked to record in a diary the time and consistency of each stool for the duration of the study. Study visits were required at the end of each one week period.

Introduction: Seven subjects were followed in this study, each of whom had had diarrhea for the 10/14 days prior to study enrollment. The 14 days experiences were averaged for each subject and compared to the average daily estimates for the 10 days prior to enrollment. These latter averages were based on recall and not on a diary. In addition to the 14 days averages, we also examined averages for 11 days (day 4-day 14), to determine whether there was any break-in period.

Results: Comparison of Average Daily Pre- and Post-Treatment Experiences among 7 Subjects Enrolled in this study showed:

	Total Stools	Number Watery	Number Soft	Number formed
Pre-treatment	5.6	3.2	2.4	0
14 Day Average	3.4	1.1	1.9	0.4
11 Day Average	3.4	1.0	1.9	0.5

Discussion: There appears to be a considerable decrease in the daily average number of stools, from 5.6 to 3.4, attributable to the treatment. There is also a corresponding decrease in the average number of watery stools, accompanied by a decrease in the number of soft and increase in the number of formed stools. There were not differences between the 14 and 11 day averages, indicating that the treatment was immediately effective. The absence of pre-treatment formed stools appears to confirm that these patients did indeed have diarrhea prior to enrollment.

It would have been preferable to have a pre-treatment diary so that the comparison (baseline) averages were not based on recall. In addition, some questions regarding improvement in quality of life and ability to function would have been desirable. Perhaps the latter can still be determined.

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