

port of a person infected with human immunodeficiency virus with the nutritional product disclosed herein impedes the apoptosis of CD4 cells. That is to say this nutritional support does not absolutely eliminate apoptosis of CD4 cells, but it appears that some component of the nutritional product interferes with the transmission of signals to CD4 cells which initiate apoptosis. It is believed that the soy protein hydrolysate used in the nutritional product provides some agent, perhaps a peptide, which results in this beneficial biological effect. Enterally providing this soy protein hydrolysate in a therapeutically effective quantity is believed to impede the apoptosis of CD4 cells in a person infected with immunodeficiency virus.

In addition to the above assessments of immune status, immunoglobulin levels for IgG, IgM, and IgA were also assessed at both baseline and after six weeks of supplementation at follow-up. No statistical differences were observed for each of these parameters at baseline when control and new product supplemented patients were compared. However, after six weeks of supplementation, each immunoglobulin level had increased. IgG, although increased in both groups, were not significantly increased in either group. However, the increase in IgG in the control group resulted in a mean value which was outside of the clinically normal range, while the increased mean value in the group fed the new product remained within normal clinical ranges. As was the case of IgG, IgM mean levels were also increased in both groups (statistically elevated in the group fed the new product). However, mean IgM levels in both groups remained within the normal clinical range. IgA were statistically elevated in both the control and the group fed the new product after six weeks.

TABLE 10 presents the change in the average number of bowel movements per day for the control and new product groups. Interestingly, enteral supplement appeared to decrease the mean number of bowel movements per day in both supplement groups. Although not statistically significant, the average number of bowel movements per day decreased by almost 1 per day in both groups after six weeks of supplementation. When the data from both groups were pooled together the average number of bowel movements per day were significantly decreased at follow-up from baseline. This is an interesting finding since enteral supplementation has not commonly been shown to result in a decrease in average number of bowel movements per day, but rather has been reported to be associated with an increase in this parameter. In addition to subjectively recording the average number of bowel movements per day, patients also provided detailed information with regard to stool consistency. There were no significant differences between the two study groups with regard to stool consistency either at baseline or after six weeks of supplementation. Furthermore, the respective nutritional supplements appeared to have no effect on the change from baseline with regard to stool consistency.

Another important clinical outcome variable measured in this study was the Karnofsky score. The Karnofsky score provides a subjective assessment of quality of life made by a patient's personal physician. TABLE 10 presents the change in the Karnofsky scores for the control and new product supplemented groups. At baseline, both study groups were nearly identical with regard to functional status (76 vs. 80 for the control and new product group respectively). However, although not statistically different, it is clear that the average

Karnofsky scores in the control group declined to a larger degree (21%) than those of the new product group (9%) over the course of the six week study.

The only biochemistries which demonstrated clinically significant changes were creatinine and blood urea nitrogen (BUN). Serum creatinine, although not statistically significant, increased from  $1.0 \pm 0.1$  to  $1.1 \pm 0.1$  mg/dL in the new product group after six weeks of supplement use while no change was observed in the control group. Conversely, BUN significantly increased from 14 to 15 mg/dL in both the control and new product groups. This increase in BUN was only statistically significant in the control group. Together, these observations suggest that the patients receiving the control supplement had a larger degree of protein breakdown as compared to the new product group and that the new product group was better able to increase muscle mass during the course of the study than the controls (as indirectly evidence by an increased creatinine level after six weeks of supplementation).

In an attempt to assess the enterotrophic effects of the new product and its constituent soy protein hydrolysate (SPH), fish oils, and soluble fiber system, terminal duodenal biopsies were obtained in a subset population of patients enrolled in this study. Six control patients and 7 patients fed the new product had baseline and six week follow-up biopsies obtained via direct endoscopy. Biopsy samples were fixed in glutaraldehyde and processed for electron microscopic analysis. No significant differences either between groups at baseline and follow-up or between change from baseline for the respective supplement groups were observed for microvillus height, microvillus diameter and microvillus surface area.

Standard anthropometric variables and their respective calculated body composition parameters were recorded. The data clearly demonstrate no significant differences or changes between any of these parameters for both study groups. It should be noted, however, that although no significant improvements were observed, both supplements were able to maintain individual anthropometric variables as well as body compartments including fat mass, fat-free mass, and percent body fat. Based on the fact that the patients enrolled in this study were reporting significant weight loss (10% from usual) upon entry into the study, this alone provides clear evidence that enteral supplementation can reduce or prevent the progressive weight loss associated with the progression of AIDS.

Another very important and costly consequence of HIV-infection and/or AIDS is the requirement of multiple hospitalizations. Five of the 22 control group patients (23%) required at least one additional hospitalization during the course of this six week study while none of the new product supplemented patients required an additional hospitalization ( $p < 0.5$ ). The cost of a single hospitalization for treatment of AIDS related complications is enormous. This finding therefore warrants further investigation.

What is claimed is:

1. A liquid nutritional product for enteral nutritional support of a person infected with human immunodeficiency virus comprising:

(a) a first source of protein comprising a soy protein hydrolysate having a molecular weight partition, as determined by size exclusion chromatography, wherein 30-60% of the particles have a molecular weight in the range of 1500-5000 Daltons;