Final Report for the Study:

Effect of Spirulina on Immune Response

by

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Study Subjects and Design

Twenty-eight subjects were enrolled in the study in the Fall of 2003. The study was postponed twice after discussion with the study sponsor concerning the potential invalidation of the study from the administration of flu shots. Some, but not all subjects had flu shots, and received them at various times. As a result of the postponements, some subjects were unable to participate. The high cost of the blood analyses to be performed for this study necessitated not replacing those subjects.

Twenty-two healthy subjects began the study in January, eight males and 14 females, ranging in age from 45 to 84 years. 19 subjects completed the study, 15 on the Treatment and four on the Placebo. Three subjects (all females) dropped out of the study for personal reasons that prevented them from participating.

The subjects received either spirulina or a placebo and took 10 tablets a day, divided into two or three doses, for eight weeks. Fasting blood samples were taken at baseline and at the conclusion of the eight weeks. The blood was stored appropriately and transported by courier to Specialty Laboratories in Santa Monica, California for analysis.

The following analyses were completed on all blood samples:

- White Blood Cell Count
- Total Lymphocyte
- Total Lymphocyte Count
- % Dual CD56/CD16
- Absolute Dual CD56/CD16
- Natural Killer Cell Function

Compliance

Subjects recorded their tablet intake on a "Tablet Log" for the entire eight weeks. Compliance was very high. Seven subjects reported not missing a single tablet. Four subjects reported missing a dose for one day only, 2 or 5 missed tablets total. Four subjects reported missing a dose for two days, with a total of 2 to 10 missed tablets. One subject reported missing a dose for three days, for a total of 15 missed tablets. One subject reported missing a dose for four days, for a total of 18 missed tablets. And one subject reported missing a dose for five days, for a total of 35 missed tablets. 15 subjects reported missing 2 or fewer days, and fewer than 10 tablets missed in the eight weeks.

Illnesses

Of the 4 participants in the placebo group, 3 had no illnesses or infections, and 1 had a cold. Of the 15 participants in the treatment group, 9 had no illnesses or infections, 3 had a cold, 1 had shingles, 1 had an allergy flare up, and 1 had the flu or food poisoning.

Results

The subjects' weights were unaffected by the participation on the study; only 2 subjects' weights changed 5 pounds or more in eight weeks. All of the subjects reported ease in taking the tablets, with no reported difficulties or complaints. All subjects rated the tablets high in acceptability.

The means, standard deviations and percent changes for all blood analyses for the treatment and placebo groups are summarized in Table 1 and 2, respectively. Mean percentage changes are also illustrated in Figures 1 and 2.

Table 1. Mean ± SD and Percent Changes for the Treatment Group

Measurements	**Mean ± SD**		**% Change**	**P value**
	Baseline	End of Study		
WBC (10E9/L)	5.9 ± 1.4	6.4 ± 1.9	+ 8	-
Total Lymphocytes (%)	33.6 ± 10.5	30.5 ± 8.2	- 9	-
Total Lymphocyte count (/uL)	1994 ± 844	1947 ± 872	- 2	-
% Dual CD 56/CD 16	17.4 ± 5.4	15.7 ± 4.8	- 2	-
Absolute Dual CD 56/CD 16 (/uL)	343 ± 179	300 ± 151	-13	<0.05
Natural Killer Cell Function (LU)	62 ± 38	79 ± 57	+ 27	-
Natural Killer Cell Function/ Absolute Dual CD56/CD16	0.18 ± 0.21	0.26 ± 0.38	+46	<0.02

Table 2. Mean ± SD and Percent Changes in for the Placebo Group

Measurements	**Mean ± SD**		**% Change**	**P value**
	Baseline	End of Study		
WBC (10E9/L)	6 ± 2	6 ± 1	+ 4	-
Total Lymphocytes (%)	43 ± 12	37 ± 11	- 5	-
Total Lymphocyte count (/uL)	2767 ± 1388	2475 ± 1030	- 11	<0.05

% Dual CD 56/CD 16	14 ± 8	18 ± 14	+ 29	<0.05
Absolute Dual CD 56/CD 16 (/uL)	308 ± 62	341 ± 104	+ 11	-
Natural Killer Cell Function (LU)	44 ± 13	78 ± 49	+ 74	-
Natural Killer Cell Function/ Absolute Dual CD56/CD16	0.14 ± 0.21	0.23 ± 0.47	+58	-

The Wilcoxon Signed Rank Test (non-parametric paired comparison) was performed to compare end-of-study values with baseline values for the spirulina (treatment) group and the placebo group. The results of the test for the treatment group showed no significant changes in any of the blood analysis except for Absolute Dual CD 56/CD 16, which decreased of ~ 13% ($P < 0.05$), and the Natural Killer Cell Function/Absolute Dual CD56/CD16 ratio, which increased of 46% ($P<0.02$).

In the placebo group, the only significant changes ($P<0.05$) observed were for Total Lymphocyte Count, which decreased of ~ 11%, and Percent Dual CD 56/CD 16, which increased of ~29%. It is important to note that the mean Percent Dual CD 56/CD 16 for the placebo group at the end-of-study visit (18%) was above the normal range (<16%).

Mean Percent Changes
in Treatment and Placebo Groups after Eight Weeks

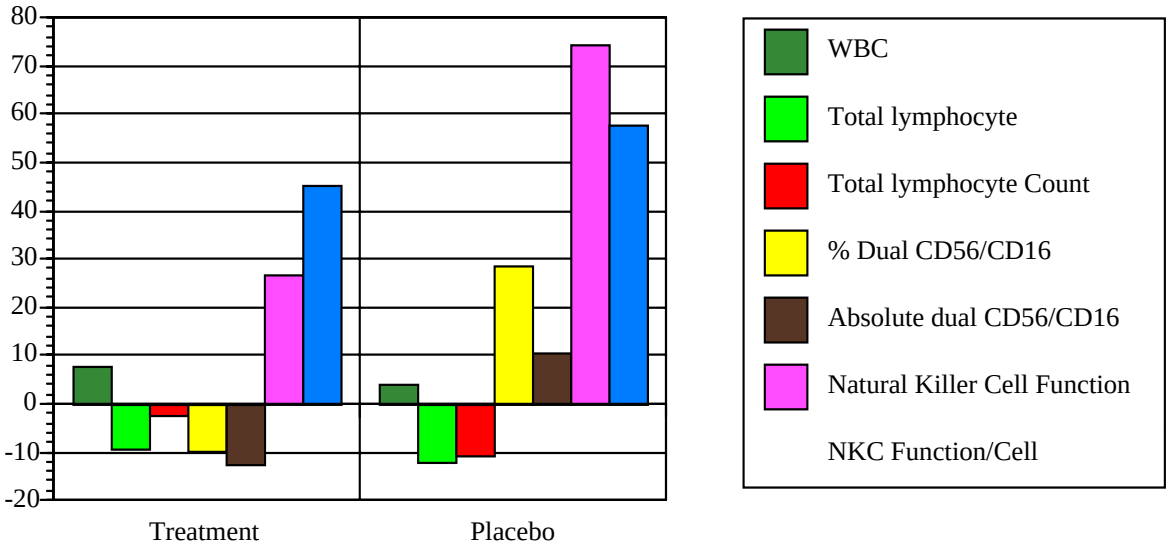

Fig 1. Mean percent changes in the treatment and placebo groups after 8 weeks.

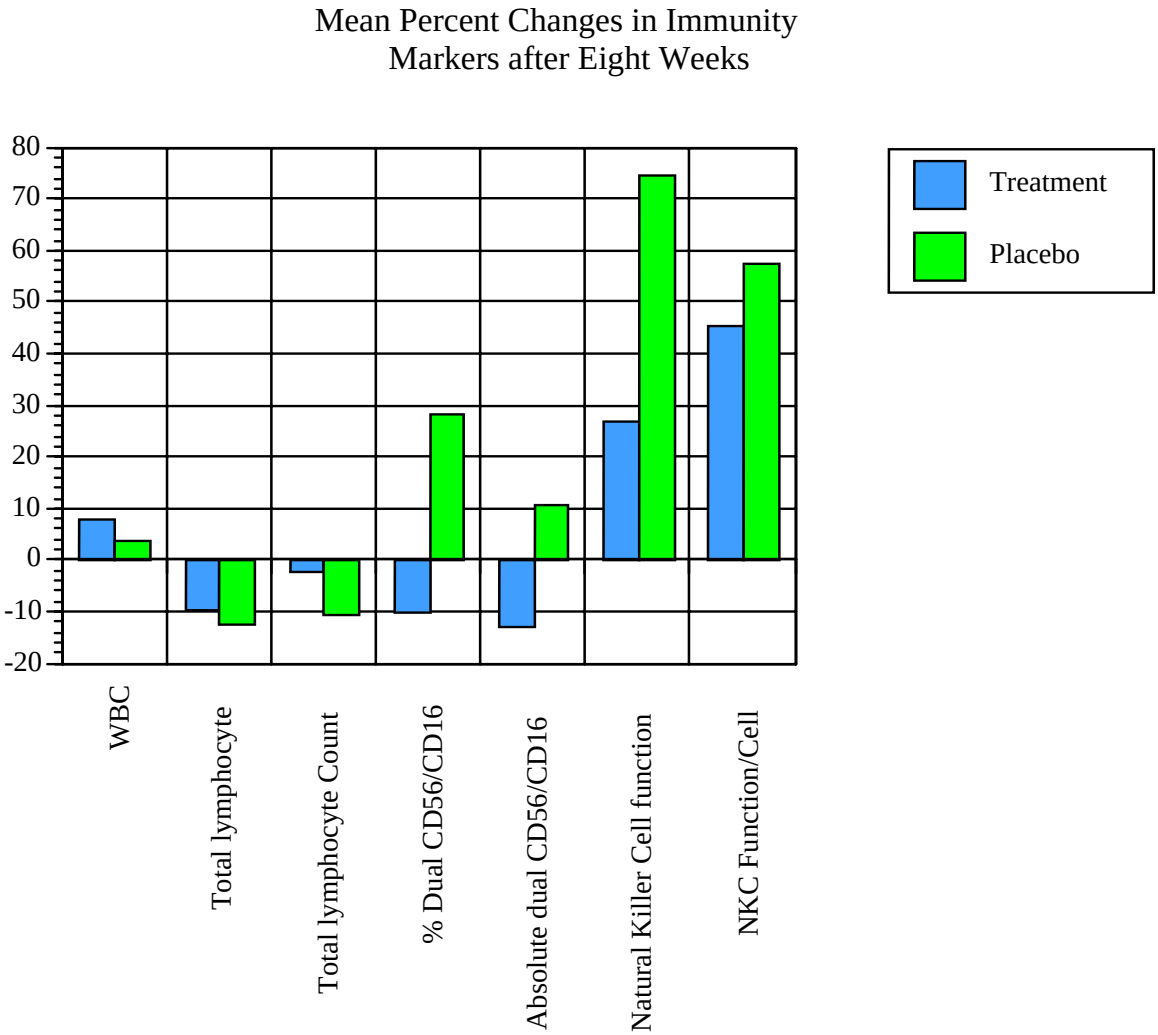

Fig 2. Mean percent changes in immunity markers after 8 weeks.