FINAL REPORT

Company Great North Star Group Inc.

Assessment of the Bioavailability of Omega Gold Seal Based Omega-3 Supplement in Human Subjects

Objective

The trial objective was to assess the ability of seal oil to improve the profile of phospholipid fatty acids in humans by increasing EPA, DPA and DHA levels in healthy human subjects consuming the supplement for a period of 28 days. The purpose of doing a trial of this nature is because of the belief that an improvement in fatty acid profile will provide cardiovascular protection to the population.

Subjects and Methods

This study was a short-term prospective cohort study in which all subjects were in the treatment group. Healthy male and female volunteers between the ages of 18 and 70 years were recruited for the study. To be eligible for participation, individuals were required to refrain from consuming any flax, fish or seal oil supplements, other than those distributed during the trial, for at least two months prior to the trial

Exclusion criteria included the following:

- Pre-existing diseases or illness
- Allergies to marine life
- Females who are pregnant or lactating, or females of child-bearing potential who are not using effective birth control
- Loss or donation of the following amounts of whole blood:
    1. 50-300 mL within the last 30 days.
    2. 310-500 mL within the last 45 days
    3. >500 mL within the last 56 days

After signing a letter of consent, subjects were measured for height and weight, and fasting blood was collected from each subject by venipuncture, for fatty acid analysis. Subjects received a two-week supply of OmegaGold seal oil, as well as a daily diary in which to record any adverse events. Subjects were instructed to consume 9 capsules of seal oil per day, evenly spread throughout the day, preferably with meals. Each capsule provides approx. 100-110 mg omega-3 fatty acids, so the 9 capsules provides approx. 1000 mg omega-3 fatty acids.

Each subject returned to the lab at day 14 and day 28 of the study, after a 12 hr. fast, bringing with them any leftover capsules, and their adverse reaction diary. The same measurements from day 0

were repeated, and on day 14 the subjects received a further 2-week supply of seal oil. Their diaries were examined for any adverse events and returned to them.

RESULTS

All 25 subjects completed the study. During the study there were no significant changes in weight for any of the study subjects. The age range of the subjects was 19-56, with an average age of 25.3 years. There were eight males and 17 females in the study. Statistical analysis of the phospholipid fatty acid data is shown in Table 1.

Table 1. Mean serum phospholipid fatty acids (wt. %) on Day 0, Day 14 and Day 21 (Mean ± SEM)

Fatty acid*	Day 0	Day 14	Day 28
LA	20.71±0.42	20.57±0.58	20.73±0.51
ALA	0.08±0.03	0.04±0.01	0.12±0.02
AA	10.06±0.28	9.69±0.24	9.56±0.27
EPA	0.87±0.09	1.49±0.12	1.77±0.11
DPA	0.78±0.06	0.90±0.07	0.90±0.05
DHA	3.37±0.19	4.50±0.20	4.74±0.17
Omega-3	5.34±0.29	7.12±0.33	7.71±0.26
Omega-6	34.87±0.39	33.92±0.46	33.66±0.50
Omega-3/Omega-6 ratio	0.16±0.01	0.21±0.01	0.23±0.01
AA/EPA ratio	14.23±1.25	7.42±0.57	6.00±0.49

* Abbreviations LA: linoleic acid; ALA: alphalinolenic acid; AA: arachidonic acid; EPA: eicosopentaenoic acid; DPA: docosapentaenoic acid;

When the changes in mean phospholipid fatty acids from day 0 to day 14 to day 28 were compared, there were several significant differences, as seen in Table 2.

Table 2 Statistically significant differences in serum phospholipid fatty acids from Day 0 to Day 14, Day 0 to Day 28 and Day 14 to Day 28

Fatty acid	Day 14 – Day 0	Day 28 – Day 0	Day 28 – Day 14
LA	NS*	NS	NS
ALA	NS	NS	p=0.0025
AA	NS	p=0.0502	NS
EPA	p<0.0001	p<0.0001	p=0.0008
DPA	NS	NS	NS
DHA	p<0.0001	p<0.0001	NS
Total Omega-3	p<0.0001	p<0.0001	p=0.0071
Total Omega-6	p=0.0197	p=0.0144	NS
Omega-3/Omega-6 ratio	p<0.0001	p<0.0001	p=0.0341
AA/EPA ratio	p<0.0001	p<0.0001	p=0.0119

*NS = no significant difference at a p-level of 0.05

There were no significant differences in LA or DPA, and only a modest significant reduction in AA level from day 0 to day 28. ALA level was significantly increased on day 28, compared to day 14. There were highly significant differences, from day 0 to day 28, in DHA and total Omega 3 levels, as well as the ratio of Omega 3 to Omega 6 fatty acids and the AA to EPA ratio. DHA, Omega-3 levels and the Omega-3/Omega 6 ratio all increased, while the AA/EPA ratio decreased. The small reductions in Omega-6 levels, from day 0 to day 28, and from day 0 to day 14 were also significant, although not as highly significant as the other indices. There were also significant increases in total Omega 3 levels, the Omega-3 to Omega-6 ratio, and the AA to EPA ratio, from day 14 to day 28, showing that it appears to take more than 14 days for maximal changes in phospholipid fatty acids to take place.

ADVERSE EVENTS

Several subjects complained of headaches for the first few days of the supplementation. Out of the 25 subjects in the study, 13 complained of mild to severe headaches. However, 2 of the subjects were migraine sufferers, and they specified that their headaches were migraines. Three others had aches and pains, from exercise or a previous injury, associated with their headaches, and for 2 subjects the headaches were associated with symptoms of the common cold. One person had a stomach ache on 5 different occasions, over a 9-day period, and two subjects expressed concerns about a “thick” head.

SUMMARY AND CONCLUSIONS

This study was designed to determine the ability of seal oil to improve the profile of phospholipid fatty acids in humans by increasing EPA, DPA and DHA levels in healthy human subjects. Although highly significant changes in EPA and DHA levels were observed. DPA levels did not change significantly.

Based on the Simon Paper in the American Journal of Epidemiology, and the LeMaitre Paper in the American Journal of Clinical Nutrition, Omega Gold Seal Oil reduces the risk of heart disease by 32% and reduces the risk of death from heart attack by 70%.

May 31st, 2007

Trial Managed By:

Nutrasource Diagnostics Inc.
Suite 712
304 Stone Road West
Guelph, Ontario
N1G 4W4

Trial Conducted At:

Human Nutraceutical Research Unit
University of Guelph
Guelph, Ontario
N1G 2W1