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ORIGINAL RESEARCH

Clinical Trial conducted at the University of Guelph, by the Human Nutraceutical Research Unit

The Supplement Immunocare™

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ABSTRACT

A randomized, double blind, placebo-controlled clinical trial to determine the effects of Immunocare™ supplement, (containing plant sterols, pine bark antioxidants and essential fatty acid complex), on specific immune parameters and cardiovascular indices in both men and women with non-food allergies.

The supplement appears to have effect on immune parameters, in particular basophils and Il-6 levels. Given these results this supplement would appear to have the potential to substantially alleviate allergic responses.

The supplement also significantly reduced circulating levels of LDL-cholesterol and increased circulating levels of HDL-cholesterol. There was a significant decrease in the ratio of TC/HDL and in the ratio of LDL/HDL-cholesterol, which corresponds to a decrease in cardiovascular risk, as these ratios are markers for a reduction in the risk for developing atherosclerosis.

SUMMARY OF GUELPH TRIAL

This trial was to determine the effects on specific immune parameters and cardiovascular indices of the supplement Immunocare™ containing plant sterols, pine bark antioxidants and an essential fatty acid complex. The trial was conducted at the University of Guelph as a randomized, double blind, placebo-controlled clinical trial with 20 subjects over 28 days.

RESULTS

Immune Parameters

The effects of the supplement on immune parameters are presented in Table 1. A number of studies support the belief that human basophils play an important role in allergic inflammation. Mast cells and basophils express the high affinity receptor for IgE (FcepsilonRI) and play a central role for IgE-associated immediate hypersensitivity reactions and allergic disorders. During allergic reactions, basophils migrate from the blood compartment to inflammatory sites, where they act as effector cells in concert with eosinophils. Basophils release histamine during inflammation and allergic reactions.

Table 1: *The effects of Immunocare™ supplementation on specific immune parameters in experimental and placebo groups from day 0 to day 28*

Immune Parameters	Immunocare Day 0	Immunocare Day 28	Immunocare Difference Day 28-Day 0	Control Day 0	Control Day 28	Control % Difference Day 28-Day 0
IgE	472	451	-4.4%	1335	1127	-15.6%
DHEA	6.44	6.44	0 %	4.93	4.77	-3.2%
Cortisol	507	584	15.2%	490	498	1.6%
Cortisol/DHEA	94.06	108.36	15.2%	160.66	141.44	-12%
IL-6	1.261	0.937	-25.7%	1.318	1.179	10.5%
WBC	7.41	7.24	-2.3%	7.28	7.13	-9.8%
Lymphocyte Count	2.16	2.24	3.7%	2.56	2.60	1.6%
Segmented Neutrophil Count	4.65	4.39	-5.6%	4.11	3.97	-3.4%
Monocytes	0.33	0.34	3.0%	0.35	0.31	-11.4%
Eosinophils	0.24	0.20	-16.7%	0.23	0.20	-13.0%
Basophils	0.23	0.01	- 95.6%**	0.13	0.04	- 69%

** statistically significant, $p<0.05$

The participants in the treatment group, when compared to the control group, showed a significant reduction in basophil count, while the reduction seen in the control group was non-significant. A reduction in basophil count may indicate a reduction in histamine release.

The immune system also responds to stressors by causing certain immune cells to secrete the pro-inflammatory cytokines, Interleukin-1 (IL-1) and Interleukin-6 (IL-6). These cytokines are

both involved in inflammation and IL-6 in particular is thought to worsen the symptoms of autoimmune diseases and fibromyalgia. Interleukin-6 has been found to act as a growth factor in several tumors and some viruses also use IL-6 to replicate. Interleukin-6 also causes calcium to be released from bone, promoting osteoporosis. We must control the release of these cytokines if we want to enhance immunity and reduce degenerative diseases.

It was noted in the pilot trial that the pro-inflammatory cytokine IL-6 levels showed a substantial reduction in the treated group when compared to the control group. Although the drop in the IL-6 levels in the treatment group was not statistically significant, a larger study with more subjects, over a longer period of time may show significance.

Immunocare has demonstrated that it has an effect on histamine-containing basophil counts and a reduction of IL-6 levels, and consequently may substantially alleviate symptoms associated with airborne allergens, asthma and allergic rhinitis. Further studies are recommended, with a larger patient participation and a longer trial period to investigate other areas of immunological response.

Cardiovascular Parameters.

The effects of the supplement on lipid and lipoprotein parameters and cardiovascular indices are illustrated in **Tables 2 and 3**

Table 2: *The effects of Immunocare™ on blood lipid parameters in experimental and placebo groups from day 0 to day 28.*

Blood Lipid Parameters (mmol/L)	Immunocare Day 0	Immunocare Day 28	Immunocare % Difference Day 28-Day 0	Control Day 0	Control Day 28	Control % Difference Day 28-Day 0
Total Cholesterol	4.36	4.13	-5.3%	4.87	4.91	8.2%
LDL	2.27	1.93	-15.0%**	2.85	2.87	0.7%
HDL	1.63	1.70	4.3%	1.48	1.41	-4.7%
TG	1.00	1.09	9.0%	1.18	1.38	16.9%

**statistically significant, $p<0.05$

Table 3: *The effects of Immunocare™ supplementation on specific cardiovascular ratios in experimental and placebo groups from day 0 to day 28.*

Cardio-vascular Parameter Ratios	Immunocare Day 0	Immunocare Day 28	Immunocare % Difference Day 28-Day 0	Control Day 0	Control Day 28	Control % Difference Day 28-Day 0
TC/HDL	2.88	2.61	-9.4%**	3.50	3.56	1.7%
LDL/HDL	1.58	1.30	-17.7%**	2.11	2.10	-0.5%
TG/HDL	0.66	0.68	3.0%	0.85	1.02	20.0%

**statistically significant, $p<0.05$

The specific objective of this portion of the trial was to determine the effects of the supplement Immunocare™ on blood lipid parameters. Significant reduction was noted in the overall LDL levels of the treatment group from day 0 to day 28. Perhaps what is more interesting is the increase, though not statistically significant, in HDL levels compared with a relative decrease in the placebo group.

However it is the ratios of various lipids and lipid proteins rather than the absolute values that are important in assessing cardiovascular risk, and consequently these ratios were calculated and tabulated.

A significant decrease in the ratio of TC/HDL, and in the ratio of LDL/HDL cholesterol, in the Immunocare™ group, was noted. A decrease in these ratios corresponds to an associated decrease in the risk of cardiovascular disease (CVD). These ratios are markers for a reduction in the risk of developing atherosclerosis. **Consequently it is our opinion that these results indicate that Immunocare™ could be very beneficial to the health of hypercholesterolemic individuals at risk of developing CVD.**

CONCLUSIONS

Immunocare and its components appear to have an effect on immune parameters and, in particular, in basophils and possibly IL-6 levels. Given these changes, Immunocare would appear to have the potential to substantially alleviate allergic responses.

Immunocare™ could also have an effect in auto-immune diseases such as Crohn's disease or rheumatoid arthritis, or in the ability of subjects to resist the common cold virus, although studies on these particular populations would be required to verify possible beneficial effects.

This study verified that Immunocare™ supplement is effective in reducing circulating levels of LDL-cholesterol and increasing circulating levels of HDL cholesterol. It is of interest to note that there was a significant decrease in the ratio of TC/HDL, and in the ratio of LDL/HDL cholesterol, in the Immunocare™ group. A decrease in these ratios corresponds to an associated decrease in cardiovascular disease (CVD) risk, because these ratios are markers for a reduction in the risk of developing atherosclerosis. Consequently, these results would be of considerable benefit to the health of hypercholesterolemic individuals at risk of developing CVD.