

ABSTRACT

A clinical trial was developed in order to assess the ability of **Ganogen**[®] to improve Immune system function in young children by including **Ganogen**[®] into their food matrix. A yogurt enriched with 500 mg per dose of **Ganogen**[®] (Beta-glucans and Ganoderic acids biotechnologically obtained from *Ganoderma lucidum* (Reishi)), was produced. No probiotics or other nutritional ingredients were added to the yogurt. The yogurt was administered through controlled research methodologies to a population of 167 children associated with a childcare foundation in the city of Medellín, Colombia, ranging in age from 2-5 years for a test period of 12 weeks.

To establish the benefit of **Ganogen**[®], it was necessary to divide the study population into two groups. One of the groups received the yogurt enriched with **Ganogen**[®] while the control group received the yogurt without the functional ingredient (placebo). Blood samples were drawn at study onset and upon completion of the test period. Measurements of specific immune system cell levels in the blood; Leukocytes, T Lymphocytes (CD3), T helper cells (CD4), cytotoxic T cells (CD8), B cells and Natural Killer cells (NK) were performed and analyzed against pre-study levels and between groups.

RESULTS

A total of 125 children completed the study and were included in the statistical analysis. The relevant characteristics of the groups were comparable at the start of the intervention (61 children in the group where the product was enriched with **Ganogen**[®] and 64 children in the placebo group). During the 12 weeks of monitoring and intervention no secondary events related to the ingestion of the yogurt were reported.

IMMUNE CELL MODULATION ANALYSIS

TOTAL LYMPHOCYTE COUNTS

An increase of 11% in total Lymphocyte count was evidenced in the group of children who consumed the yogurt with **Ganogen**[®], compared to the initial measure. On the contrary, a decrease of 7.5% relative to initial values was observed in the group of children who consumed the placebo ($p < 0.001$).

Figure 1.

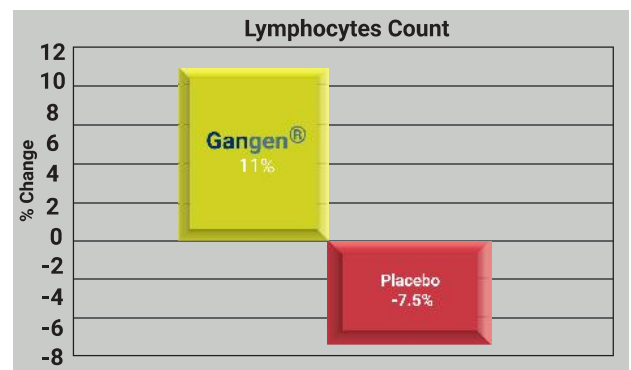


Figure 1. Comparison of % change in total Lymphocytes count in both groups

CD4 CELLS

Functionally, CD4 cells participate in the control and elimination of some bacteria and parasites. CD4 cell counts increased by an average of 12.3% in the group that consumed **Ganogen**[®], while a decrease of 4.5% was observed in the placebo group, as compared to initial measured values ($p < 0.001$). **Figure 2.**

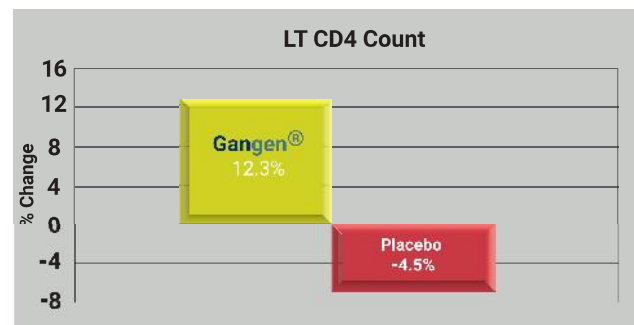


Figure 2. Comparison of the % change in the count of CD4 in both groups



Progal-bt



Progal_bt



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Effects of Ganogen® in children

CD3 CELL COUNT

An increase of 13.3% in CD3 cells in the group that consumed **Ganogen**® was observed, while the placebo group demonstrated a decrease of 6.1% ($p < 0.001$). **Figure 3**.

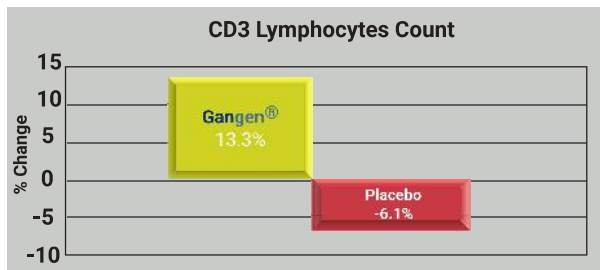


Figure 3. Comparison of the % change in the count of CD3 cells in both groups

CD8 CELL COUNT

The main function of the CD8 cells is to destroy cells infected by intracellular pathogens using cytotoxic mechanisms such as viruses and some bacteria. In addition, they have a very important role in the control of tumor cells. The group receiving the yogurt with **Ganogen**® reported an increase of 15.2% in CD8 cells compared to the baseline measures, while in the placebo group there was a decrease of 5.3% ($p = 0.001$). **Figure 4**.

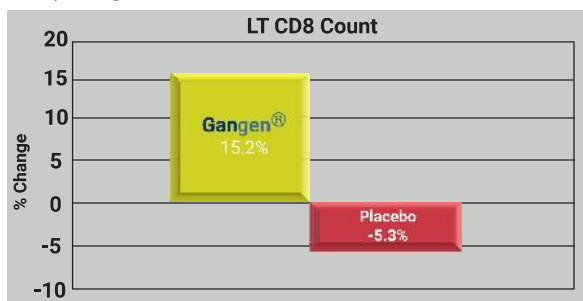


Figure 4. Comparison of the % change in the count of CD8 cells in both groups



These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

IMMUNOGLOBULIN A

An analysis of the serum Immunoglobulin A (IgA) was made. Unlike the cells previously described and evaluated, this is not a cellular component, but a molecule secreted by a mature stage of B-cells. This molecule is mainly found in the mucous membranes (respiratory system, gastrointestinal tract, urinary tissue, etc.). It represents a key line of defense against pathogens to which we have been previously exposed (reinfections and vaccination processes). Regarding this molecule we found that the group of children, who received the yogurt with **Ganogen**® presented a statistically significant increase in the serum concentration of IgA (**Figure 5**), an effect that was not found in the group of children who received the yogurt without the functional ingredient (placebo).

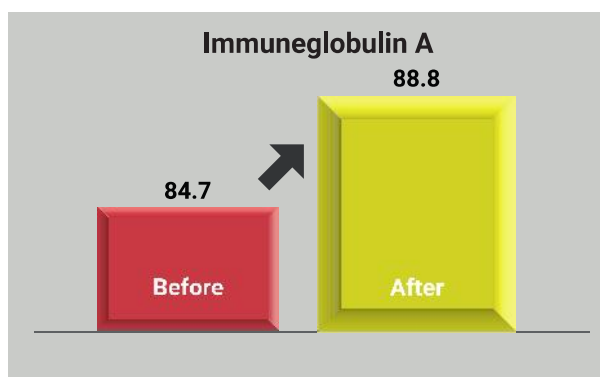


Figure 5. Before-and-after Comparison of IgA in the group that consumed Yogurt with **Ganogen**®

CONCLUSIONS

This study showed that the yogurt enriched with **Ganogen**® increased the number of CD4, CD3 and CD8 cells, Total Lymphocytes and Immunoglobulin A (IgA), demonstrating the clinical effectiveness of **Ganogen**® in strengthening the children's immune system. In addition, the product was well tolerated and no adverse effects were observed during the 12 weeks of consumption.

It is important to note the measured decrease in immune system markers across all categories in those children not taking **Ganogen**®. This weakening of the immune system is believed to be directly related to the relentless mental, neurological and physical stresses of their extreme immediate socio-economic environment. This suggests that **Ganogen**® not only helps the body defend against pathological attacks but also contributes in ways that fortify overall well-being.