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Alkemy™

Review & Summary of Clinical Trial of Alkemy™ vs Gatorade® in Exercise Induced Dehydration

Alkemy™ is a proprietary hydrating water product (patent pending) which is formulated to provide hydration at least comparable to that of the leading marketed sports beverage. The objective of this clinical trial was to measure the effects of hydration after the consumption of Alkemy™ *versus* Gatorade®. The study design evaluated hydration after controlled exercise regimens designed to induce a 2 to 3% reduction in body weight. Exercise was conducted in a controlled physical environment with temperature range of 91° - 104°F and relative humidity range of 40% - 56%. The study was designed such that all volunteers received each test product in a cross-over fashion on two separate occasions, with the two test visits separated by at least three days.

This clinical trial was conducted using an approved protocol utilizing an open label, comparative, cross-over study at a recognized clinical research center, in conformity with FDA Good Clinical Practices (GCP) guidelines after gaining the approval of an independent IRB committee.

Healthy female volunteers (non-smoking, 18–45 years of age) with a history of at least six months of exercise experiences were enrolled in this clinical study.

Alkemy™ is a proprietary product which is a purified water with added minerals and electrolytes. This alkalizing, hydrating product (patent pending process) was studied to determine if it is comparable to that of the leading market sports beverage. Alkemy™ is non-caloric with a pH of 8.2, while Gatorade®, which is similar in sodium electrolyte concentration but differs in amounts of other electrolytes and minerals, has a pH of 3.5, far more acidic, and contains 50 calories per 8 ounce serving, as well as 14 grams of sugar per 8 ounces.

At the end of each 60-minute exercise cycle, subjects were dosed with one of the two test products (Alkemy™ or Gatorade®) defined as the amount of 1.2 pints (2.5 cups) for each pound of bodyweight lost during the previous exercise regimen.

Blood and urine samples were collected prior to the start of exercise and again at 30, 60, 90 and 120 minutes post dosing. Body weight was measured pre-exercise, and at the end of exercise just prior to dosing and at 30, 60, 90 and 120 minutes post-dose. The hydration effects of the test products (Alkemy™ and Gatorade®) were evaluated by serum osmolality and hematocrit, as well as by serum sodium, serum potassium, urine specific gravity, bodyweight and levels of thirst as measured by a 10 point scale. Additionally subjects were polled for a rating of taste of the two test products and any comments made during the study by the subjects were collected.

The results of this clinical trial indicated the rehydration characteristics of the two products were similar. Observations from the trial indicated a few minor, non-significant variations. Gatorade® administration resulted in a slightly greater recovery of serum osmolality, serum sodium and urine specific gravity. Alkemy™ administration resulted in slightly greater recovery of hematocrit and serum potassium. The two products were virtually identical with respect to noted thirst levels. None of the differences between products were statistically or clinically significant. No product was demonstrated to be superior to the other with respect to any of the measured efficacy endpoints.

Comments by the subjects were more favorable for Alkemy™ than for Gatorade®, noting that Alkemy™ tended to taste better and Gatorade® tended to make subjects feel "uncomfortably full". Alkemy™ is a non-caloric product whereas Gatorade® contains calories (sugar etc).

Conclusion

The Alkemy product was found to be equal in hydrating power to Gatorade®, in all the physical and physiological parameters studied, following exercise induced dehydration under carefully controlled conditions. Subject comments favored the Alkemy™ product over Gatorade® in terms of taste preference and statements of feeling 'over full'