## Clinical evidence activated clinoptilolite suspension removes heavy metals without removing vital electrolytes

Funded by a grant from Wellness Industries, LLC.

Abstract: This study was designed to evaluate the ability of activated clinoptilolite suspended in water (ACS) to remove heavy metals from the body without the removal of electrolytes. The protocol utilized two treatment groups, each consisting of eleven healthy men aged 36 to 70 years. Volunteers were given a commercially available version of the study substance for seven days (Group 1) and 30 days (Group 2) and urine samples were collected at specified time points in the study. Also, serum samples were obtained from five individuals in each group and serum electrolytes were measured prior to and after taking the product. Participants in both groups had increased concentrations of heavy metals in the urine with the peak excretion at around day 4. No clinically significant alterations in serum electrolyte levels were seen at either seven or 30 days on ACS. In conclusion, this study demonstrates that the daily use of an activated clinoptilolite suspension represents a potentially safe and effective way to remove toxic heavy metals from the body through increased urinary excretion without removing clinically detrimental amounts of vital electrolytes.

Method: A total of 33 male subjects aged 35 to 71 years were divided into two experimental groups, group 1 (n = 11) and group 2 (n = 11), and one control group (n = 11). Each experimental group consumed a commercially available dietary supplement consisting of an activated clinoptilolite suspension. The product, a suspension in water, was taken by mouth as 15 drops, twice per day. The control group consumed an equal volume of a placebo solution, prepared as 50 ng/ml magnesium silicate and 1 mg/ml citric acid in purified water. Group 1 was evaluated for seven days while Group 2 and the control group were evaluated for 30 days. All participants consulted their personal physicians to insure they had no medical conditions that would preclude participation in this study before reviewing and signing informed consent forms. Inclusion in the study required that participants not be diabetic; not have any serum electrolyte imbalance; not be on any metal-based therapy (such as lithium or gadolinium contrast); not be under therapy for heavy metal toxicity, then or for three months prior; and tested positive, above a predetermined threshold value, for at least four of the nine metals in the test panel. Once informed consent was obtained, each participant provided a 50 ml urine sample, taken from the first morning elimination and frozen at -20 °C.

This became the baseline urine sample, referred to as time 0 (T0). Each participant also submitted to a basic metabolic panel for serum electrolytes, creatinine and glucose prior to beginning the study. Five participants from each experimental group and the control group submitted to a second metabolic panel after completing the study. At the end of the study, each urine sample was thawed on ice and then divided into three aliquots. First, for all metals except mercury, urine was diluted 1:1 with a solution of 15% HNO3 in ultrapure H20 and containing yttrium as an internal standard (S1). For mercury analysis, a second sample was prepared by diluting the urine 1:1 with a solution of 15% HCl, 0.25% cysteine and 1.75% EDTA with yttrium as an internal standard (S2). The final sample remained unaltered (S3) and was utilized for urinary creatinine analysis. Heavy metal content was measured by inductively coupled plasma mass spectroscopy (ICP-MS) using a SCIEX 6100 DRC (PerkinElmer, Wellesley, MA) using standard methods. Each measurement was repeated three times. Measurements of urinary creatinine levels and serum electrolyte levels were performed in a commercial clinical laboratory using standard protocols and reagents. Urinary creatinine results were expressed as mg/dL, serum creatinine levels were expressed as mmol/L, serum glucose concentration was expressed as mg/dL and serum electrolyte concentrations were expressed as mmol/L.

**Results** Analysis of participant age, serum electrolyte levels, serum creatinine levels and urinary creatinine levels using ANOVA revealed that there were no significant differences between or among the experimental groups and the control group on any of the baseline parameters prior to beginning the study. Analysis of the serum electrolyte panels collected prior to and after the study revealed no significant changes from creatinine, glucose, potassium, magnesium, calcium, sodium, or chloride baseline levels following use of the activated clinoptilolite suspension for seven days. The 30-day and the control groups also remained unchanged.

**Conclusion:** This study presents clinical evidence supporting the use of an activated clinoptilolite suspension to safely and effectively increase the urinary excretion of potentially toxic heavy metals in healthy volunteers without negatively impacting the electrolyte profiles of the participants. Significant increases in the urinary excretion of aluminum, antimony, arsenic, bismuth, cadmium, lead, mercury, nickel and tin were observed in the subjects participating in the two study groups as compared to placebo controls. Since spectroscopic analysis showed no detectable contamination of the activated clinoptilolite suspension with the metals being evaluated, it is reasonable to assume that this observation was attributable to increased excretion of stored toxins and certainly led to a reduction in the overall toxic metal body burden of the participants. It is notable that the degree of response, as well as relative timing of the response, to the ACS supplement was variable among participants. This was not completely unexpected and can be explained by a number of variables, from the innate differences in physiology among the individuals within each group to differing levels of compliance with the instructions for taking the ACS supplement. However, for all participants of this study, consumption of an ACS supplement for either seven or 30 days resulted in a measurable enhancement of urinary excretion of heavy metals in subjects that demonstrated a positive excretion phenotype by testing positive for those toxins in the prescreening urinalysis. The kinetics of excretion observed in this study, which revealed a several-fold increased peak in urinary excretion of toxic metals at four days for both groups taking ACS, implies that the supplement may serve initially to help clear free, exchangeable heavy metal cations from the body, while the continued excretion of these toxic species, albeit at reduced levels, out to 14 days, and in some cases out to 21 and even 30 days, suggests that use of an ACS supplement for a longer time may result in removal of sequestered toxins from various tissues. Across the globe, heavy metal toxins and other pollutants are ubiquitous in our environment. These pollutants exist in our air, water, and food supplies, our workplaces, even our homes and automobiles. The human physiological system has many mechanisms in place for excreting these contaminants, through sweating, incorporation into hair and nails, defecation and urination. However, the ability to excrete and eliminate these environmental toxins is highly variable by individual phenotype as well as the nature of the contaminant. As such, these toxins are also metabolized and processed to render them "less toxic" through processes including sequestration in adipose, brain and muscle tissue. This buildup often occurs very slowly and can eventually result in clinically significant levels of heavy metals that result in disease. The increased awareness of the role of chronic heavy metal poisoning in the clinical manifestation of a broad array of disorders and syndromes has resulted in an increased focus on therapies that remove or reduce these toxins. The use of activated clinoptilolite suspension to remove these ubiquitous toxins from the body presents an alternate modality of therapy to traditional treatment through chelation. Additionally, the use of a safe and natural product like activated Clinoptilolite suspension may provide a solution to the many challenges presented by the more traditional therapies, such as the requirement for extended time spent in a medical facility and the associated costs incurred; undesirable side effects; and unpredictable efficacy. Further studies using activated clinoptilolite suspension in individuals suffering both chronic and acute exposure to high levels of heavy metal toxins, from environmental, occupational and lifestyle-associated sources, is warrant