

Double-Blind Study Evaluating the Effects of Exercise Plus 3-Acetyl-7-oxo-dehydroepiandrosterone on Body Composition and the Endocrine System in Overweight Adults.

Carlton M. Colker, M.D.¹, Georgeann C. Torina², Melissa A. Swain², Douglas S. Kalman².
Department of Medicine, Greenwich Hospital¹. Peak Wellness, Inc². Greenwich, CT 06830

Introduction: Recently the American College of Physicians has indicated that all middle age women should be screened for sub-clinical thyroid disease upon their yearly physical (1). Sub-clinical hypothyroidism is associated with weight gain, sluggishness, fatigue and a cluster of other symptoms. Previously, 3-Acetyl-7-oxo-dehydroepiandrosterone (7-KetoTM, Humanetics Corporation) has been shown to normalize an induced hypothyroid state in lab animals (2). 7-KetoTM is also known to promote futile cycling. Regular exercise is known to help promote and maintain weight loss (3). **Methods:** Thirty overweight (BMI 31.9 ± 6.2) adults (Age 44.5 ± 11.5) were randomized into a prospective, double-blind, placebo controlled eight week study. Fifteen subjects received 7-KetoTM 100 mg twice per day whereas the other 15 subjects received a matching placebo. All subjects exercised three times per week, 60 minutes per session of cross-training (aerobic and anaerobic) under the supervision of an exercise physiologist. Study participants underwent serum multiple assay chemistry testing, body composition analysis (7-site, caliper), blood pressure, and dietary analysis at baseline, week four and at week eight. **Statistics:** Baseline characteristics were analyzed with both the Wilcoxon and Fisher's exact test. Descriptive analyses were also analyzed via the Wilcoxon test. Mean changes over time within each group were analyzed by Signed Rank test and across group analysis were carried out by use of the Wilcoxon test. **Results:** The exercise plus 7-KetoTM group lost a significant amount of body weight as compared with the exercise plus placebo group (-2.88 kg, $p=0.012$). When analyzed as a per four week interval, the 7-KetoTM group lost 1.44 kg per interval, whereas placebo lost 0.49 kg ($p<0.01$). In terms of actual body composition changes, the exercise plus 7-KetoTM group lost 1.8% body fat as compared to 0.57% for the placebo group ($p=0.02$). When viewed as a change in body fat per four week interval, the 7-KetoTM group lost 0.89% body fat per interval as compared to 0.29% for the placebo ($p=0.003$). In terms of effects on the thyroid, triiodothyronine (T3) activity increased significantly in the group receiving 7-KetoTM and not the placebo (+17.88 ng/dl vs. 2.75 ng/dl; $p<0.05$), there were no significant changes in either TSH or T4. There were no significant changes in blood sugar, testosterone, estradiol, liver, renal function tests, vital signs, or overall caloric intake over the eight week study. Nor were there any subjective adverse effects reported throughout the study. **Discussion:** Our results indicate that one hour of cross-training three times per week supplemented with 200 mg of 7-KetoTM per day yields a significant reduction in both body weight and body fat. Furthermore, 7-KetoTM elevated T3 significantly, which may indicate an effect on basal metabolism. Despite the effect on T3, there was no significant change in TSH, indicating no untoward down regulation or negative feedback on thyroid function within the time-frame of the study. Previous work with 7-KetoTM in rats has demonstrated that it fosters proton leakage and induces thyroid hormone (3). This may, in part, explain the results of the study. **References:** 1. Helfand M. *Ann Int Med* 129(2):144-158, 1998 ; 2. Bobyleva V. *Arch Biochem Biophys* 341(1):122-128, 1997 ; 3. Miller WC. *Int J Obes Relat Metab Disord* 21(10): 941-947, 1997.