



**Kronos Longevity Research Institute (KLRI)**  
<http://www.KronosInstitute.org>

## **Press Release**

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### **Clinical Study on the Effects of Growth Hormones and Sex Steroid Administration in Healthy Aged Men and Women**

A study to be published in the Nov.13 issue of the Journal of the American Medical Association shows that combining human growth hormone and sex steroids may have additive positive effects for older people, including increased muscle mass, decreased fat, increased strength and increased oxygen capacity. Due to adverse health effects, however, researchers do not recommend this combination for therapeutic uses in healthy older men and women.

This is the most comprehensive clinical study of human growth hormone and the first to evaluate the effects of recombinant human growth hormone and/or sex steroid administration on body composition, muscle strength, physical endurance and adverse outcomes in men and women age 65 and older. The research took more than six years to complete. Approximately 2,000 healthy men and women ages 65 to 88 were assessed for eligibility and 131 participants were selected (57 women and 74 men).

The subjects took part in a 26-week, randomized, placebo-controlled trial, during which they were placed into one of four groups: 1) those who received growth hormone and sex steroids; 2) those who received only growth hormone; 3) those who received only sex steroids; or 4) those who received only placebos (control group). The sex steroids administered were estrogen/progestin for women and testosterone for men.

"Effects of Growth Hormone and Sex Steroid Administration in Healthy Aged Men and Women" was jointly conducted and co-authored by Dr. S. Mitchell Harman, founding director of the Kronos Longevity Research Institute and Dr. Marc Blackman, Clinical Director of the National Center for Complementary and Alternative Medicine, National Institutes of Health and other researchers.

#### **SUMMARY OF FINDINGS**

- Growth hormone increased lean body mass in men and women.

- Growth hormone decreased the amount of body fat in men and women.
- Growth hormone combined with testosterone, but not growth hormone alone, increased strength in men. Strength did not increase in women.
- Growth hormone combined with testosterone increased maximal oxygen capacity (endurance) in men.
- Growth hormone caused glucose intolerance in men, some of whom became diabetic, but not in women.
- Numerous adverse effects were associated with growth hormone. Most participants developed at least one adverse effect. These included symptoms of carpal tunnel syndrome, leg edema, and joint pain or stiffness.

Due to the numerous adverse effects associated with growth hormone, the study did not provide supportive evidence that it is safe to give growth hormone to older, healthy adults; nor is the evidence sufficient to indicate that growth hormone produces clinically beneficial effects to healthy, older individuals.

According to Dr. Harman, "Until several issues are resolved, growth hormone treatment for age-related changes in healthy adults should be confined to approved, controlled clinical trials."

## **ABOUT DR. S. MITCHELL HARMAN**

**Dr. Harman**, a graduate of Emory University, received two doctoral degrees from the State University of New York Health Sciences Center at Brooklyn and trained in internal medicine at Yale and in endocrinology at the National Institutes of Health (NIH).

He served as both the acting clinical director of the National Institute on Aging and the chief of endocrinology for the NIA's Laboratory of Clinical Physiology. Dr. Harman founded the NIA laboratory for the study of aging of the male and female reproductive hormone systems. He served as an NIH investigator with the Intramural Program of the NIA, where the growth hormone research was carried out. He was also an officer in the U.S. Public Health Service and a faculty member at Johns Hopkins University School of Medicine for 25 years.

Dr. Harman is board certified in both internal medicine and endocrinology. He is the author or co-author of one book and 19 book chapters, many in major textbooks of medicine, geriatric medicine and endocrinology. He is an internationally recognized expert on hormones and aging, and has authored more than 70 original research papers. [Please see Dr. Harman's biography for additional information.]

## **ABOUT KLRI**

KLRI is a not-for-profit 501 (c)(3) organization that conducts state-of-the-art clinical translational research on the prevention of age-related diseases and the extension of healthier human life. Translational research is the critical link between findings from the basic research laboratory and corresponding improvements in clinical care.

Some of KLRI's current studies include: Validation of Oxidative Stress Assessments; Omega-3 Fatty Acids and Endocrine/Immune Dysfunction in Humans; and Coenzyme Q10 and Myocardial Function in Patients on Statin Drugs. KLRI will soon launch studies focusing on

testosterone replacement and cardiovascular disease.

For more information, visit KLRI's Web site at [www.kronosinstitute.org](http://www.kronosinstitute.org).

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