



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

## **Press Release**

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### **KRONOS LONGEVITY RESEARCH INSTITUTE (KLRI) ANNOUNCES STUDY TO EXAMINE TESTOSTERONE'S EFFECTS ON THE PROGRESSION OF ATHEROSCLEROSIS IN AGING MEN**

**KLRI Will Collaborate with the University of California at Los Angeles and Drew University School of Medicine on this 5-Year Study**

PHOENIX (August 4, 2003) - **Kronos Longevity Research Institute (KLRI)** announced plans to begin a five-year study examining **Testosterone's Effects on the progression of Atherosclerosis in Aging Men** (TEAAM Study). Atherosclerosis is a medical condition in which fatty material is deposited along the walls of arteries. This fatty material thickens, hardens and may eventually block the arteries.

KLRI is collaborating with the University of California at Los Angeles and Drew University School of Medicine. In addition to determining whether testosterone replacement increases the risk of atherosclerotic heart disease, the TEAAM Study will examine whether physiologic testosterone replacement in older men improves lean body mass, muscle function, cognitive function, and health-related quality of life.

"A lack of information in two areas has prevented researchers from formulating general recommendations for the use of testosterone replacement in older men," said Dr. S. Mitchell Harman founding director of KLRI and lead investigator for the TEAAM Study. "First, the effectiveness of testosterone in improving physical function, quality of life and other health-related outcomes has not been convincingly demonstrated. And second, while there is agreement that short-term administration of testosterone replacement is safe, the long-term risks, such as atherosclerosis, remain unknown."

Previous studies have demonstrated that total and free testosterone levels decline with advancing age in men, with a significant number of men meeting the criteria for hypogonadism (low testosterone levels) in their sixties and seventies. Researchers believe the loss of testosterone may lead to decreases in bone and muscle strength and contribute to frailty and poor quality of life in later years.

#### **TEAAM STUDY DESIGN**

The TEAAM Study will be a randomized, placebo-controlled, double-blind examination of healthy male volunteers ages 60 and older with testosterone levels less than 450 ng/dL.

Researchers will recruit 320 subjects (160 at KLRI's Phoenix-based research facility and 160 in the Los Angeles area) over a two-year period and the selected men will be treated for three years.

The subjects will be stratified by age (60-75 and >75) and placed into two groups. The first group will receive AndroGel®, an FDA-approved testosterone gel for external application. The second group will receive placebo gel consisting of the alcohol base used in AndroGel® without the testosterone.

All subjects will be seen during 10 formal evaluation sessions for data collection procedures and five additional brief visits for study monitoring, including a compliance check, a review for adverse effects, and a brief physical exam.

## **ABOUT DR. S. MITCHELL HARMAN, DIRECTOR OF KLRI**

Dr. Harman, a graduate of Emory University, received his medical and 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 the aging effects 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 is a CAPT (retired) in the U.S. Public Health Service and a faculty member at Johns Hopkins University School of Medicine for 25 years.

Dr. Harman holds a dual certification from the boards of internal medicine and endocrinology. He authored 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 also 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 Testosterone Replacement and Cardiovascular Disease. KLRI will soon launch studies focusing on Coenzyme Q10 and Statin Drugs on Heart and Muscle Function.

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