

NIH Looking for a Few Good Old Men with Low Testosterone to Join Clinical Trial

National clinical trial will determine if low testosterone causes serious problems in senior citizens

Nov. 4, 2009 – A new clinical trial is seeking men age 65 and older to help determine if low testosterone contributes to serious problems in older men, including a decrease in the ability to walk, loss of muscle mass, less strength, decreased vitality, decreased sexual function, impaired cognition, cardiovascular disease and anemia. Many of these have become accepted results of "aging."

Testosterone normally decreases with age, but in some men, low levels of testosterone may contribute to these debilitating conditions. The new national clinical trial will test whether these conditions can be favorably affected by testosterone therapy.

The National Institute on Aging (NIA), part of the National Institutes of Health, this week announced the start of this large-scale clinical trial to evaluate the effect of testosterone therapy on older men.

Led by the University of Pennsylvania School of Medicine and conducted at 12 sites across the nation, the Testosterone Trial will involve 800 men age 65 and older with low testosterone levels.

"We know that, as men get older, a significant proportion are unable to carry out activities of daily living and experience decreased physical and cognitive function and decreased independence," said NIA Director Richard J. Hodes, M.D.

"We do not know the extent to which low levels of testosterone may contribute to these conditions."

A 2004 report by the Institute of Medicine, *"Testosterone and Aging: Clinical Research Directions,"* noted several important unanswered questions about the effects of testosterone therapy. The NIA is aiming to answer these questions by testing the effectiveness of testosterone therapy in older men with low testosterone levels and one of the following conditions: impaired walking, low vitality, sexual or cognitive dysfunction.

A key consideration is the use of testosterone as a therapy for certain conditions, rather than as a preventive measure.

The NIA is the primary source of support for this trial. Additional funding is being provided by the National Heart, Lung, and Blood Institute (NHLBI); the National Institute on Neurological Disorders and Stroke (NINDS); the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and Solvay Pharmaceuticals, which is also supplying the study drug.

The Testosterone Trial will include five separate studies.

At each of the 12 sites, men 65 and older with low serum testosterone and at least one of the following conditions — anemia, decreased physical function, low vitality, impaired cognition or reduced sexual function — will be randomly assigned to participate in a treatment group or a control group.

Treatment groups will be given a testosterone gel that is applied to the torso, abdomen, or upper arms; control groups will receive a placebo gel. Serum testosterone will be measured monthly for the first three months and quarterly thereafter up to one year.

Participants will be tested on a wide range of measures to evaluate physical function, vitality, cognition, cardiovascular disease, and sexual function.

"This study is important because testosterone products have been marketed for many years as treatments for a variety of conditions," said Evan C. Hadley, M.D., director of NIA's Division of Geriatrics and Clinical Gerontology, which is the primary funder of the trial.

"We hope this trial will establish whether testosterone therapy results in clear benefits for older men."



The University of Pennsylvania School of Medicine as the lead institution for the trial and will serve as coordinating center for the study sites. Peter J. Snyder, M.D., professor of medicine in the Division of Endocrinology, Diabetes and Metabolism at Penn, is the principal investigator and will oversee trial activities.

"This is an unprecedented opportunity for older men to learn more about themselves and at the same time help find out if testosterone will improve some of the afflictions of old age," said Dr. Snyder.

Recruitment of study participants will begin in November of 2009. Men age 65 and older who are interested in participating should call the site closest to them. Men living within a 50-mile radius of the study centers, listed below, are especially encouraged to participate.

Participating institutions and their phone numbers include:

- University of California, Los Angeles; 310-222-5297
- University of California, San Diego; 877-219-6610
- Boston University; 617-414-2968
- University of Pittsburgh; 800-872-3653
- Albert Einstein College of Medicine, Bronx, N.Y.; 718-405-8271
- Baylor College of Medicine, Houston, Texas; 713-798-8343
- University of Minnesota, Minneapolis; 612-625-4449
- Yale University, New Haven, Conn.; 203-737-5672
- University of Alabama at Birmingham; 205-934-2294
- VA Puget Sound Health Care System and University of Washington School of Medicine, Seattle; 206-768-5408
- Northwestern University, Evanston, Ill.; 877-300-3065
- University of Florida, Gainesville; 866-386-7730, 352-273-5919

Additional information about the study is available at www.ttrial.org and at clinicaltrials.gov.

Background Information

The NHLBI plans, conducts, and supports research related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. The Institute also administers national health education campaigns on women and heart disease, healthy weight for children, and other topics. NHLBI press releases and other materials are available online at www.nhlbi.nih.gov.

The NINDS (www.ninds.nih.gov) is the nation's leading funder of research on the brain and nervous system. The NINDS mission is to reduce the burden of neurological disease — a burden borne by every age group, by every segment of society, by people all over the world.

The NICHD sponsors research on development, before and after birth; maternal, child, and family health; reproductive biology and population issues; and medical rehabilitation. For more information, visit the Institute's Web site at <http://www.nichd.nih.gov/>.

The NIA leads the federal effort supporting and conducting research on aging and the medical, social and behavioral issues of older people. For more information on research and aging, go to www.nia.nih.gov.

The National Institutes of Health (NIH) — The Nation's Medical Research Agency — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

<http://www.seniorjournal.com/NEWS/Health/2009/20091104-NIHLookingForAFew.htm>