The study will be done on men over 65 and at 12 sites around the country.

By Diane Chun
Staff writer
Published: Wednesday, November 18, 2009 at 6:01 a.m.
Last Modified: Tuesday, November 17, 2009 at 9:46 p.m.

University of Florida researchers are looking for a few good men - quite a few, actually - with low testosterone levels to join a national study that could help them function better in everyday life.

It's called "The T Trial," and the study of 800 men over the age of 65 will be conducted at 12 sites around the country.

Testosterone is the main male hormone, and as men age, their testosterone levels drop off. Although it's most often related to sex drive, testosterone also drives a healthy metabolism, promotes muscle and bone strength, energy level and memory.

"We want to see if replacing testosterone in men in whom it is decreased would avert many of the symptoms related to lowered testosterone," said Dr. Marco Pahor, principle investigator in the study and director of the UF Institute on Aging.

Lower-than-normal levels of the hormone in the blood can lead to low energy, sexual dysfunction, physical impairment and anemia. Up to five million men in the United States are estimated to have low testosterone levels.

Testosterone products have been marketed for years as treatments for a variety of conditions. The sales have been aimed at men who did not necessarily have low testosterone levels.

"We hope this trial will establish whether testosterone therapy results in clear benefits for older men," said Dr. Evan Hadley. Hadley is director of the National Institute on Aging's Division of Geriatrics and Clinical Gerontology, which is the primary funder of the nationwide trial.

In older men whose testosterone levels have dropped as a result of aging, the potential benefits and safety of such hormone therapy are still unknown.

The Testosterone Trial seeks to find answers in five areas: sexual function, physical performance, mental sharpness, vigor and anemia. All have been shown to be associated with the age-related decrease in testosterone levels.

To take part in the study, men must be 65 or older, have testosterone levels below a certain concentration as measured by a blood test, and have symptoms and measurable signs of movement restriction, low libido or low vitality.

Those who are chosen will be in the study for two years, and will be compensated for participating. They'll receive study-related health and medical screening at no cost. Men with prostate cancer are not eligible.

Participants will be split into two groups, with each asked to apply a gel to the skin daily for the first year of the study. One group will get a prescription gel containing testosterone, called AndroGel.

The second group will get a gel that does not contain testosterone. Neither the participants nor the study staff will know which of the gels they receive. In the second year of the study, the men in both groups will make one follow-up clinic visit and take one phone call in which they will answer a number of study-related questions.
Other institutions taking part in the study are the Albert Einstein College of Medicine, the Baylor College of Medicine, Boston University, Northwestern University, the University of Alabama-Birmingham, the University of California-Los Angeles, the University of California-San Diego, the University of Minnesota, the University of Pittsburgh, the University of Washington and Yale University.