

Can testosterone therapy aid older men?

Study tests hormone gel on men older than 65

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By Mark Roth, Pittsburgh Post-Gazette

As men age, their testosterone levels naturally drop.

But for some men, the male sex hormone may sink so low that they not only lose all interest in sex, but suffer more falls, have memory problems and experience anemia.

A new national study at the University of Pittsburgh and 11 other sites will now explore whether applying testosterone gel to the abdomen, torso or upper arms can reverse those effects.

It may also offer some early signals on whether testosterone gel could put men at increased risk of prostate cancer, since the hormone has been linked in the past to that malignancy.

The study is being funded by the National Institutes of Health and coordinated at the University of Pennsylvania. It will recruit 800 men over age 65 who have especially low levels of testosterone, and will give half of them testosterone gel treatments, and other half a placebo ointment.

The men will be tracked for two years to see if the group getting testosterone has significant improvement in vitality and well-being, said Dr. Peter Snyder, principal investigator and an endocrinology researcher at Penn.

Previous studies have linked low testosterone to thinking difficulties, low energy, falls, brittle bones, anemia and even heart problems.

The evidence from these studies is "tantalizing but not convincing," Dr. Snyder said. "I think there is considerable evidence that testosterone treatment might do good in all these areas, and I think it's worthwhile spending our time finding out."

Dr. Jane Cauley, the main local investigator and an epidemiology professor at Pitt, said that sexual desire, energy, strength and a clear mind are "all important for a person's quality of life, and what we will be doing is to look at these overall markers of well-being."

The study has been years in the making, Dr. Snyder said, and when it was first suggested by the national Institute of Medicine in 2003, it was quite controversial.

The institute's recommendation came out at around the same time that a large study of hormone replacement therapy in post-menopausal women, the Women's Health Initiative, showed that the female hormone treatments put women at greater risk of getting breast cancer, heart disease and other ailments. That prompted the New York Times to ask in an editorial: "Can American men be rushing into the same reckless use of hormones that brought grief and anxiety to so many unsuspecting women? That disquieting possibility is raised by a new report that laments a huge upsurge in testosterone replacement therapy for men despite a paucity of evidence that it is safe or beneficial. One wonders whether another medical debacle is in the making."

The main possible drawback, Dr. Snyder said, is an increase in prostate cancer, and to guard against that, the study will not admit any men who have had prostate cancer or are at risk for getting it, and it will remove men from the study who develop blood markers of prostate cancer risk.

To qualify, men over 65 first must fall into one of three groups: they must have difficulty walking a quarter mile; they must have low energy; or they must have a lack of sexual interest, Dr. Cauley said.

They will then be tested on two different days for blood testosterone levels, which must be lower than 250 nanograms per deciliter. Normal testosterone levels in younger men are 500 to 900 nanograms per deciliter.

The testosterone gel is made by the Solvay Chemical and Pharmaceutical Group. It is already approved by the Food and Drug Administration to treat men who were born with abnormally low testosterone or have low levels because of such conditions as diabetes, high blood pressure or obesity.

The main goal of the study is to get rid of the doubts about testosterone treatment, Dr. Snyder said.

"We think it's likely that the men treated with testosterone will have some beneficial effects, but we don't know for sure."

For more information, call the University of Pittsburgh at 1-800-872-3653.

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