

Endocrine Society calls for large-scale studies to evaluate testosterone therapy risks

7 February 2014

According to a statement issued today by the Endocrine Society, the risks and benefits of testosterone therapy for older men with declining levels of the hormone need to be fully evaluated.

The statement comes in response to recent studies that have raised concerns about the safety of [testosterone therapy](#) in older men with a history of heart disease. Two retrospective analyses and one randomized trial supported by the Veterans Health Care System, and the National Institutes of Health found a higher rate of cardiovascular events in men who received testosterone and had preexisting heart problems. The U.S. Food and Drug Administration has announced it plans to evaluate the safety of testosterone therapy.

Testosterone is approved for the treatment of hypogonadism due to known diseases of the testes, pituitary and hypothalamus. Although the use of testosterone therapy is increasing, the treatment has not been approved for the treatment of age-related symptoms or the age-related decline of [testosterone levels](#).

Important safety data are expected from the NIA's ongoing randomized trial examining testosterone in about 800 older men with unequivocally [low testosterone levels](#) and accompanying symptoms, including sexual and physical dysfunction. The trial's structure and careful monitoring of [cardiovascular events](#) will help provide important safety information.

The Society calls for the development of more large-scale randomized controlled trials to determine the true risks and benefits of testosterone therapy in older men.

In the statement, the Society recommends that middle-aged and [older men](#) who are considering

testosterone supplementation for age-related declines should be informed of the potential cardiovascular risks. The Society also believes that it may be prudent not to administer testosterone therapy to men who have had a cardiovascular event (such as myocardial infarction, stroke or acute coronary syndrome) in the preceding six months.

In cases where men are being treated for hypogonadism as a result of known diseases of the testes, pituitary and hypothalamus, however, patients should consult their [health care](#) providers before making any changes to their medication regimen. The Society believes testosterone is generally safe and beneficial when used to treat young, hypogonadal men with these conditions. The Society's Clinical Practice Guideline on testosterone therapy in this population is available at

<http://www.endocrine.org/~media/endsociety/Files/Publications/Clinical%20Practice%20Guidelines/FINAL-Androgens-in-Men-Standalone.pdf>.

Provided by The Endocrine Society

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