

Little evidence testosterone treatment increases the risk of cardiovascular events, most in-depth analysis suggests

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Testosterone replacement therapy appears safe in the short-to-medium term to treat a condition caused by deficiency of the male sex hormone,

according to the most comprehensive analysis of the treatment to date, published in *The Lancet Healthy Longevity* journal.

The findings suggest that men given [testosterone](#) to treat hypogonadism are at no greater risk of heart attack, stroke and other cardiovascular events in the short-to-medium term than men who do not receive testosterone treatment.

Testosterone replacement therapy is the standard treatment for hypogonadism, which can cause [sexual dysfunction](#), weakening of bones and muscles, and reduced quality of life. Risk factors for the condition include aging (as testosterone levels decline with age), obesity (BMI of 30 kg/m² or above), and diabetes.

Despite being widely used, the cardiovascular safety of testosterone treatment has until now remained unclear due to inconsistent findings. This is because most previous clinical studies have relied on aggregate data rather than individual participant data, and have not published details of individual adverse events.

Lead author Jemma Hudson from the University of Aberdeen explains, "Prescribing of testosterone for hypogonadism is increasing globally, but conflicting messages about its safety may have led to many patients not receiving the treatment. Ongoing studies should help to determine the longer-term safety of testosterone, but in the meantime, our results provide much-needed reassurance about its short-to-medium term safety. Our findings could have important implications for the treatment of men with [hypogonadism](#) worldwide."

The authors conducted a systematic review identifying 35 eligible clinical trials published since 1992, of which 17 provided individual participant data. A blinded analysis by two independent clinicians enabled the classification of every [cardiovascular event](#), allowing for a

more robust analysis of the cardiovascular safety of testosterone treatment. A meta-analysis using individual participant data from 17 studies and a further meta-analysis integrating these data with the aggregate data provided by the 18 trials that did not provide individual participant data were performed.

Among the 17 trials with individual patient data, 1,750 participants received testosterone and 1,681 were given a placebo. The average length of testosterone treatment was 9.5 months. The average age of participants was 65 years, and most were white and did not smoke. Participants' average BMI was 30 kg/m², which is considered obese.

A meta-analysis showed there were 120/1,601 (7.5%) cardiovascular events in the testosterone group and 110/1,519 (7.2%) in the placebo group across 13 trials that provided this information. Patient age, smoking or diabetes status did not affect cardiovascular risk. Similarly, there was no significant difference in mortality rate between the testosterone group (6/1,621 deaths, 0.4%) and the placebo group (12/1,537 deaths, 0.8%) across the 14 trials that provided individual patient data on mortality, but only limited data were available.

The researchers also found that testosterone significantly reduced serum total cholesterol, high-density lipoprotein (HDL), and triglycerides compared with placebo. However, there were no significant differences in serum low-density lipoprotein (LDL), blood pressure, glycemic parameters, diabetes incidence, and prostate adverse outcomes between the testosterone and placebo groups.

The meta-analysis that integrated individual participant data with aggregate data showed similar results.

The authors acknowledge some limitations to their study. There was little available data evaluating the cardiovascular safety of testosterone

treatment beyond 12 months, and the very small number of deaths recorded during testosterone trials hampered the authors' ability to analyze why they occurred. However, the longer-term safety of [testosterone treatment](#) is currently being investigated in another clinical trial. While the meta-analysis of aggregate data showed similar results to the one involving individual patient data only, it cannot be ruled out with certainty that a high number of unreported cardiovascular events in the trials that did not provide individual participant data could alter the current conclusions.

More information: Adverse cardiovascular events and mortality in men during testosterone treatment: an individual patient and aggregate data meta-analysis, *The Lancet Healthy Longevity* (2022). DOI: 10.1016/S2666-7568(22)00096-4 , [www.thelancet.com/journals/lan ... \(22\)00096-4/fulltext](http://www.thelancet.com/journals/lan.../22/00096-4/fulltext)

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