GCT-85 Testosterone Replacement in Young Male cancer Survivors (TRYMS): A six-month double-blind randomised placebo-controlled study

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Background: Young male cancer survivors have lower testosterone levels, higher fat mass and worse quality-of-life (QoL) than age-matched healthy controls. We have undertaken a double-blind, placebo controlled, six-month trial of testosterone replacement in young male cancer survivors with borderline low testosterone levels.

Methods: Male cancer survivors aged 25–50 years with morning total serum testosterone 200–350 ng/dl were recruited. Participants were randomised 1:1 to receive testosterone (Tostran 2% gel) or placebo for 26 weeks. A dose titration was performed after two weeks. The co-primary endpoints were trunk fat mass and SF36 Physical Functioning score (SF36-PF) at 26 weeks by intention to treat (ISRCTN: 70274195, EudraCT: 2011-000677-31).

Results: 136 men were recruited. At 26 weeks, testosterone treatment compared with placebo was associated with decreased trunk fat mass (−0.9 kg, 95% CI −1.6 to −0.3, $p = 0.0073$), decreased whole body fat mass (−1.8 kg, 95% CI −2.9 to −0.7, $p = 0.0016$) and increased lean body mass (1.5 kg, 95% CI 0.9 to 2.1, $p < 0.0001$). Decrease in fat mass was greatest in those with a high truncal fat mass at baseline. There was no treatment effect on SF36-PF or any other QoL scores. There was also no difference in fasting insulin: glucose ratio, fasting lipids Testosterone treatment was well-tolerated. In young male cancer survivors with low normal morning total serum testosterone, replacement with testosterone is associated with an improvement in body composition.