A Selective Androgen Receptor Modulator (OPK-88004) in Prostate Cancer Survivors: A Randomized Trial

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Clinical Trial

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Abstract

Background: Androgen deficiency is common among prostate cancer survivors, but many guidelines consider history of prostate cancer a contraindication for testosterone replacement. We determined the safety and efficacy of a selective androgen receptor modulator (OPK-88004) in symptomatic, testosterone-deficient men who had undergone radical prostatectomy for low-grade, organ-confined prostate cancer.

Methods: In this placebo-controlled, randomized, double-blind trial, 114 men, ≥19 years of age, who had undergone radical prostatectomy for low-grade, organ-localized prostate cancer, undetectable PSA (<0.1 ng/mL) for ≥2 years after radical prostatectomy and testosterone deficiency were randomized in stages to placebo or 1, 5, or 15 mg OPK-88004 daily for 12 weeks. Outcomes included PSA recurrence, sexual activity, sexual desire, erectile function, body composition, muscle strength and physical function measures, mood, fatigue, and bone markers.

Results: Participants were on average 67.5 years of age and had severe sexual dysfunction (mean erectile function and sexual desire domain scores 7.3 and 14.6, respectively). No participant experienced PSA recurrence or erythrocytosis. OPK-88004 was associated with a dose-related increase in whole-body ($P < 0.001$) and appendicular ($P < 0.001$) lean mass and a significantly greater decrease in percent body fat ($P < 0.001$) and serum alkaline phosphatase ($P < 0.001$) than placebo. Changes in sexual activity, sexual desire, erectile function, mood, fatigue, physical performance, and bone markers did not differ among groups ($P = 0.73$).

Conclusions: Administration of OPK-88004 was safe and not associated with PSA recurrence in androgen-deficient men who had undergone radical prostatectomy for organ-confined prostate cancer. OPK-88004 increased lean body mass and decreased fat mass but did not improve sexual symptoms or physical performance.

Trial registration: ClinicalTrials.gov NCT02499497.

Keywords: androgen treatment in prostate cancer; body composition; muscle performance; quality of life; sexual function.

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- Prostate-Specific Antigen-Based Screening for Prostate Cancer: A Systematic Evidence Review for the U.S. Preventive Services Task Force [Internet].

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May. Report No.: 17-05229-EF-1. Rockville (MD): Agency for Healthcare Research and Quality (US); 2018 May. Report No.: 17-05229-EF-1. PMID: 30085502 Free Books & Documents. Review.

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  Basaria S, Collins L, Dillon EL, Orwoll K, Storer TW, Miciek R, Ulloor J, Zhang A, Eder R, Zientek H, Gordon G, Kazmi S, Sheffield-Moore M, Bhasin S. Basaria S, et al. J Gerontol A Biol Sci Med Sci. 2013 Jan;68(1):87-95. doi: 10.1093/gerona/gls078. Epub 2012 Mar 28. J Gerontol A Biol Sci Med Sci. 2013. PMID: 22459616 Free PMC article. Clinical Trial.

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  Wilt TJ, MacDonald R, Rutks I, Shamliyan TA, Taylor BC, Kane RL. Wilt TJ, et al. Ann Intern Med. 2008 Mar 18;148(6):435-48. doi: 10.7326/0003-4819-148-6-200803180-00209. Epub 2008 Feb 4. Ann Intern Med. 2008. PMID: 18252677 Review.

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