

# Patients with metastatic prostate cancer living significantly longer

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Access to therapies approved over the last decade has significantly lengthened median survival times in patients with metastatic hormone-sensitive prostate cancer. That conclusion comes from a large

randomized clinical trial that tested a new treatment for these patients.

The S1216 study was conducted by researchers from SWOG Cancer Research Network, a cancer [clinical trials](#) group funded by the National Cancer Institute (NCI). It tested the efficacy of the drug orteronel in these [patients](#), pairing it with [androgen deprivation therapy](#) on the investigational arm and comparing that combination to androgen deprivation [therapy](#) plus bicalutamide. The results are published in the *Journal of Clinical Oncology*.

Although the study missed the primary endpoint of a 33 percent improvement in overall survival (OS), it also showed an unprecedented median OS of 70 months in the control arm, the highest ever reported for these patients on a non-intensified androgen deprivation therapy arm. This OS is a 24 month improvement over results reported in 2013 from the SWOG-9346 trial, which enrolled a nearly identical proportion of patients with extensive disease.

The researchers conclude that the primary reason for this extended survival compared to previous studies is the life-prolonging additional treatments patients received after they completed the S1216 trial. Some 77 percent of control arm patients whose cancer progressed went on to get additional life-prolonging treatment after finishing the trial therapy, compared to 61 percent in the orteronel arm.

"We are seeing the benefit of the advancements made in advanced prostate [cancer](#) therapy in the last decade, resulting in unprecedented improvements in survival of men with [advanced prostate cancer](#) in general, which is great news for our patients," said study lead author Neeraj Agarwal, MD, a SWOG investigator with the Huntsman Cancer Institute at the University of Utah.

In setting the measure of success for the trial as an improvement in OS

of at least 33 percent, the S1216 study team had worked from the assumption that median control arm OS would be 54 months, a figure that built on the SWOG-9346 results and added time to account for the anticipated impact of new drugs then being reviewed for approval. Because the actual median control arm OS exceeded this assumption by 16 months, the results did not meet the threshold for S1216 to be considered a positive trial.

Men on the orteronel arm also had significantly improved median progression-free survival (47.6 months versus 23.0 months) and [prostate-specific antigen](#) (PSA) response rates measured at seven [months](#) after the start of treatment (complete-, partial-, and no-response rates of 58, 22, and 19 percent versus 44, 31, and 25 percent); these were secondary endpoints in the trial.

**More information:** Neeraj Agarwal et al, Orteronel for Metastatic Hormone-Sensitive Prostate Cancer: A Multicenter, Randomized, Open-Label Phase III Trial (SWOG-1216), *Journal of Clinical Oncology* (2022). [DOI: 10.1200/JCO.21.02517](https://doi.org/10.1200/JCO.21.02517)

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