

Three-drug combination prolongs survival in men with metastatic, hormone-sensitive prostate cancer

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Results from an international, randomized, double-blind, placebocontrolled, phase 3 clinical trial indicate that adding the androgenreceptor inhibitor darolutamide to androgen-deprivation therapy and chemotherapy prolongs the survival of men with metastatic, hormone-



sensitive prostate cancer, a disease that is fatal in most cases. The study, which was conducted by a team led by investigators at Massachusetts General Hospital (MGH), is published in the *New England Journal of Medicine*.

Standard treatment for patients with metastatic, hormone-sensitive prostate cancer includes the addition of either the chemotherapy drug docetaxel or an androgen-receptor pathway inhibitor to androgendeprivation therapy, with the latter two treatments acting to lower the effects of androgen hormones, such as testosterone. Clinical trials that have combined all three treatments have generated conflicting results. To provide clarity, investigators designed the large, international ARASENS Trial and randomly assigned 1,306 patients with metastatic, hormonesensitive prostate cancer in a 1:1 ratio to receive the oral androgenreceptor inhibitor darolutamide or placebo, both in combination with androgen-deprivation therapy and docetaxel.

Survival rates in the two groups were compared after 533 patients had died. Patients were followed for a median of approximately 3.5 years, and those who received darolutamide had a 32.5% lower risk of dying during that time than patients not taking darolutamide. Patients taking darolutamide also experienced greater delays in developing <u>castration-resistant prostate cancer</u> (which no longer responds to treatments that lower testosterone), pain, and the need for other anti-cancer therapies. The combination of three medications did not result in more toxic effects compared with the combination of <u>androgen-deprivation therapy</u> and docetaxel alone.

"Despite progress in recent years, survival is short for patients with <u>metastatic prostate cancer</u>. Results from ARASENS are an important step forward, and triplet therapy with darolutamide should become a new standard of care for the treatment of patients with metastatic hormone-sensitive prostate cancer," says lead author Matthew R. Smith,



MD, Ph.D., director of the Genitourinary Oncology Program at the Mass General Cancer Center and an associate professor of medicine at Harvard Medical School.

More information: Matthew R. Smith et al, Darolutamide and Survival in Metastatic, Hormone-Sensitive Prostate Cancer, *New England Journal of Medicine* (2022). DOI: 10.1056/NEJMoa2119115

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