

Enzalutamide adds five months survival in late-stage prostate cancer

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Results of a phase III clinical trial of the drug Enzalutamide, published yesterday in the *New England Journal of Medicine*, show the drug extends life by an average five months in the most advanced stages of prostate cancer.

"This is a major advance. Not only do we see more [survival benefit](#) than from traditional [chemotherapy](#), but the side effects of Enzalutamide are much lower. It provides both more benefit and less harm – you get the quantification of more life, but also see quality of life improvements," says study co-author, Thomas Flaig, MD, medical director of the University of Colorado Cancer Center's Clinical Investigations Shared Resource and associate professor of medicine at the University of Colorado School of Medicine.

The study, known by the acronym AFFIRM, followed 1199 patients with [prostate cancer](#) that had progressed despite both hormonal and chemotherapy treatments, with 2/3 of patients receiving the drug Enzalutamide versus control. Median overall survival for patients in the treatment arm of the trial was 18.4 months compared to 13.6 months for patients in the placebo arm. In addition to prolonged survival, patients given Enzalutamide showed meaningful improvement in other measures including PSA blood levels, an increase from 3.0 months to 8.3 months in time until PSA progression, and an increase from 2.9 months to 8.3 months in overall progression-free survival.

The once-a-day oral drug works by blocking prostate cancer's ability to

supply itself with androgens – hormones including testosterone that otherwise drive the cancer's growth. It does this by binding to cancer cells' [androgen receptors](#) – the waving tentacles on the outsides of cells that are designed to grab specific molecules as they float past. Enzalutamide plugs these receptors, removing their ability to grab androgen.

This out-competition for space in androgen receptors is not a new strategy. But when treated with existing anti-androgen drugs, prostate cancer tends to pull androgen receptors inside the cell walls, into a cell's nucleus where the receptors are shielded from drugs but can continue to trap androgens and thus signal growth. In addition to plugging receptors, Enzalutamide inhibits this nuclear translocation.

"Prostate cancer has traditionally been viewed as having two phases," Flaig says, "first is the hormone-sensitive stage and second is the stage at which the disease is no longer dependent on hormones and we're forced to turn to more toxic chemotherapies." Even a few years ago, the use of a hormonal agent in this second phase of prostate cancer would have been viewed as futile. Beyond establishing a new treatment for advanced prostate cancer, this study also helps to redefine "hormone-refractory" prostate cancer and proves that androgen-targeted treatments continue to be relevant later into the disease process than previously believed.

"This approach represents a much more potent and effective means of targeting the androgen receptor than possible with previously available agents. While this study examined the effect of adding Enzalutamide to standard androgen deprivation therapy, future studies could explore a single agent approach with this drug to treat prostate cancer," Flaig says. Another major study to look at this pre-chemotherapy activity is underway.

"We are in a renaissance period in the medical therapy of prostate

cancer," Flaig says. "Enzalutamide is a key member of a half dozen new and emerging drugs and the challenge of the next five years is to discover how to best time and potentially combine these new agents. But even at this early stage, Enzalutamide is a game changer."

Provided by University of Colorado Denver

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