

# Promising new options for treating aggressive prostate cancer

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Cedars-Sinai Cancer investigators have identified two promising new treatment options for men with recurrent prostate cancer—both of which helped patients live longer without their disease progressing than the

current standard treatment. The results of their international Phase III clinical trial were published today in the *New England Journal of Medicine*.

"If these treatments are approved by the Food and Drug Administration, our results will be practice changing," said Stephen Freedland, MD, associate director for Training and Education and the Warschaw, Robertson, Law Families Chair in Prostate Cancer at Cedars-Sinai, and lead author of the study. "In the study, both of these new options improved metastasis-free survival while preserving quality of life."

Cancer of the prostate, a walnut-sized gland that helps make semen, will be diagnosed in 288,300 men in the U.S. in 2023, according to American Cancer Society estimates. For some, treatment may never be needed because they have a slow-growing form of the disease, but those with more [aggressive prostate cancer](#) are often first treated with surgery or [radiation therapy](#).

"Unfortunately, in about a third of those patients, the [cancer](#) recurs within 10 years," Freedland said.

Patients with aggressive recurrence are treated with androgen deprivation therapy (ADT), also known as [hormone therapy](#), which reduces the patient's production of the male sex hormone [testosterone](#). Testosterone helps prostate cancer cells grow and spread, and the hormone therapy effectively reduces the growth-stimulating effects. But Freedland said ADT has two downsides: It doesn't completely eliminate testosterone, and it can cause many side effects.

"When you go on ADT, the testosterone level in the blood is reduced, but not completely eliminated," Freedland said. "And the concern is that the testosterone that remains may still be enough to stimulate tumor growth. Also, patients don't love the idea of being on hormones."

In this study of 1,068 prostate cancer patients from 244 sites in 17 countries, Freedland and fellow investigators tested two experimental interventions—one to address each of these issues.

In the [randomized clinical trial](#), one-third of the patients received ADT plus a medication called enzalutamide, which blocks the effects of testosterone. Enzalutamide keeps any testosterone remaining in the blood from stimulating the growth of cancer cells.

Another third of the patients received enzalutamide alone. This option relied on the medication to block the effects of testosterone even though testosterone levels in the patients' blood were not reduced.

"We wanted to see whether enzalutamide on its own was so effective that we didn't need the ADT," Freedland said.

The final group of patients received ADT alone, which is the current standard treatment.

Investigators found that the combination of ADT plus enzalutamide reduced the risk of metastasis or death by 58% over ADT alone. They found that enzalutamide alone reduced the risk of metastasis or death by 37% over ADT alone. Both treatments maintained quality of life relative to the ADT alone.

"While the [combination therapy](#) offers greater risk reduction, some men might prefer enzalutamide alone. It does a good job of preventing cancer spread or death, with different side effects that may be more acceptable for some men," Freedland said.

The next step is for the makers of [enzalutamide](#) to apply for FDA approval, so the experimental therapy can come into wide use, Freedland said.

"Optimizing therapy for patients with aggressive recurrence after their [prostate cancer](#) is initially treated has been an unmet need," said Dan Theodorescu, MD, Ph.D., director of Cedars-Sinai Cancer and the PHASE ONE Distinguished Chair. "The results of this trial point the way to two options which the study showed were more effective than current standard of care, giving these patients and their providers the opportunity to choose a potentially improved course of therapy that best meets their needs."

**More information:** Stephen Freedland et al, Improved Outcomes with Enzalutamide in Biochemically Recurrent Prostate Cancer, *New England Journal of Medicine* (2023).

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