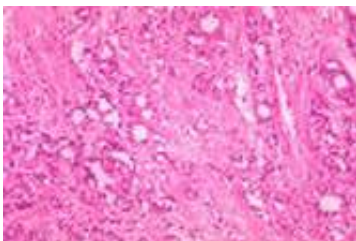


Drug may extend survival for men with advanced prostate cancer

January 29 2014, by Serena Gordon, Healthday Reporter



Study participants hadn't received any treatment with chemotherapy.

(HealthDay)—A new hormone therapy drug for men with prostate cancer may increase survival a bit and delay progression of the disease in men who have advanced prostate cancer that has been resistant to standard hormonal therapies, a new study suggests.

The study found that the [drug](#) enzalutamide increased survival by 29 percent and delayed [disease progression](#) by 81 percent in men who hadn't received any treatment with chemotherapy.

"There's new hope for men with very advanced prostate cancer," said study author Dr. Tomasz Beer, deputy director of the Knight Cancer Institute at Oregon Health and Science University in Portland. "This is a treatment with an excellent safety profile that can help men maintain quality of life and extend disease-free progression and extend survival."

The findings are scheduled to be presented Thursday at a meeting of the American Society of Clinical Oncologists, in San Francisco. The study authors reported receiving research funding from the drug's manufacturers.

The U.S. Food and Drug Administration approved enzalutamide in 2012 for use in men with advanced prostate cancer who have received chemotherapy. The drug is a type of hormone therapy called an androgen receptor blocker. Androgens are male hormones.

Enzalutamide is considered a second-generation hormone therapy. First-generation hormone therapy drugs for prostate cancer include bicalutamide, flutamide and nilutamide.

The current study included more than 1,700 men with prostate cancer that had spread to other areas of their bodies. The men's cancer also had progressed despite treatment with other types of hormone therapy. None of these men had yet been treated with chemotherapy. They had, however, been treated with surgery and radiation therapy.

Half of the volunteers were randomly assigned to receive enzalutamide and the other half received a placebo.

The study was stopped early because it was clear that enzalutamide offered a benefit over a placebo, so the drug was offered to all of the study volunteers.

"There was an 81 percent reduction in the risk of disease progression for men on enzalutamide," Beer said. "The median time to disease progression in placebo was [about four] months, but on the drug, a median time to disease progression hasn't been reached despite 20 months of follow-up."

When the study was stopped, 28 percent of those on enzalutamide had died, compared with 35 percent of those taking a placebo. The average median survival rate at the time of the first analysis was 32.4 months for those on enzalutamide versus 30.2 months for those taking a placebo.

"This drug is being used relatively early in prostate cancer, and patients can receive multiple treatments after," Beer said of the study population. Most of the men involved in the study were later treated with chemotherapy.

The drug is an oral medication, and it was well tolerated in the study. Previously published reports from when the drug was first approved suggested that the wholesale price of the medication would be about \$7,450 a month.

"This drug is already FDA-approved in the post-chemotherapy setting, though it's not yet FDA-approved for use before chemotherapy," Beer said.

Dr. Ash Tewari, chairman of urology at the Icahn School of Medicine at Mount Sinai, in New York City, said enzalutamide works three different ways to suppress androgens, making it a "triple threat."

"This study's findings are exciting, and may give us another tool to fight this cancer," Tewari said. "And it was safe, with some minor side effects but nothing unusual."

Another study scheduled for presentation at the meeting looked at men with less advanced prostate cancer. This study found that adding radiation treatment to anti-androgen therapy dropped the 10- and 15-year prostate-cancer-specific death rate for men with locally advanced prostate cancer. Locally advanced prostate cancer is cancer that has grown through the prostate, but hasn't yet traveled to other areas

of the body.

Surgery generally isn't an option for this type of cancer because it's difficult to remove all of the cancer cells.

The study, from Norwegian researchers, included 11 years of follow-up observation. Men who received hormone therapy alone had 10- and 15-year [prostate-cancer](#)-specific death rates of 18.9 percent and 30.7 percent, respectively. The rates for men who received radiation and [hormone therapy](#) were significantly lower: 8.3 percent and 12.4 percent, respectively.

Because these studies were presented at a medical meeting, the data and conclusions should be viewed as preliminary until they are published in peer-reviewed journals.

More information: Learn more about prostate cancer from the [American Cancer Society](#).

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