

For advanced prostate cancer, new drug slows disease

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A new medication proved effective in slowing the spread of metastatic prostate cancer, while helping to maintain the quality of life, in patients with advanced disease. The phase 3 study was unblinded midway, allowing patients receiving the placebo to instead take the drug because of the favorable results.

The study is the first [randomized clinical trial](#) to document expanded benefits among a particular group of [prostate cancer patients](#) in whom the disease had spread. The medication, abiraterone acetate -- marketed as Zytiga -- also delayed the development of pain and deterioration of the patients' overall condition.

The researchers say the medication could provide new treatment options.

"This drug extended lives and gave patients more time when they weren't experiencing significant pain from the disease," said the principal investigator of the international trial, Charles J. Ryan, MD, an associate professor of clinical medicine at the UCSF Helen Diller Family Comprehensive Cancer Center.

"This is an interim analysis, the final analysis should be available in 2014," he said. "But it appears that this medication may lay a foundation for the use of this drug at an earlier stage of prostate cancer, and its benefits may be able to be delivered to a much wider population of patients as a result."

Ryan will present the data on June 2 at the 48th annual meeting of the American Society of Clinical Oncology in Chicago.

Prostate cancer is the second most common form of cancer in men, with some 30,000 people annually dying from the disease. Approximately one-third of patients require no treatment, because their disease does not metastasize, or spread, while another third are treated and cured. But for the remaining patients, the cancer will recur following treatment or spread to the bones, lymph nodes or other parts of the body. Prostate cancer can turn lethal when it spreads and when it resists standard hormonal therapy.

"These results are the culmination of years of research, and will truly transform the way we take care of patients with advanced prostate cancer," said Eric J. Small, MD, a UCSF professor and chief of hematology and oncology at the UCSF Helen Diller Family Comprehensive Cancer Center. He and Ryan have collaborated on the research of this class of medication for about 9 years.

"This is a wonderful milestone in our progress in treating prostate cancer, and provides advanced prostate cancer patients everywhere with an important new weapon to fight their cancer," he said.

Last year, the U.S. Food and Drug Administration approved abiraterone [acetate](#) for men whose disease had spread and who also were resistant to standard hormonal therapy, known as castration-resistant prostate cancer (CRPC) and had received chemotherapy with docetaxel. The approval was based on a clinical trial that showed the effectiveness of the medication in post-chemotherapy patients with more advanced disease.

In the new trial, the patients' cancer had metastasized and had become resistant to initial hormone therapy, but they were not showing considerable symptoms from the disease and had not yet received any

chemotherapy.

The study involved 1,088 men at 151 cancer facilities in North America, Europe and Australia. On average, the patients had been diagnosed with prostate cancer five years earlier.

The patients were administered Zytiga in combination with low-dose prednisone. The trial was unblinded in March after it was determined that the drug delayed the need for chemotherapy and for pain medications, improved survival and [quality of life](#). Zytiga also slowed the spread of cancer from an average of 8 months in the placebo group compared to approximately double the time in the treatment group. The medication demonstrated such clear advantages to patients that an independent monitoring committee recommended that patients receiving the [placebo](#) be allowed to receive the active drug.

"This trial with a well-tolerated oral agent slowed the progression of the disease while helping to delay suffering and maintaining quality of life in patients with advanced prostate cancer," said Ryan who has been researching the drug since 2004 and helped design the [phase 3](#) study.

"These are the goals that we are moving toward in cancer treatment. The treatment of advanced prostate cancer is undergoing a rapid transformation, and this drug is a key component of that transformation."

The medication, by Janssen Research & Development, LLC targets prostate cancer by blocking the production of hormones produced by the cancer that can stimulate its growth. The medication was first created in a British lab in the 1990s. The manufacturer warns that it should be used with caution in patients who have a history of cardiovascular disease, high blood pressure, low blood potassium, and fluid retention.

Provided by University of California, San Francisco

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