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Hormone-depleting drug shows promise against localized high-risk prostate tumors

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A hormone-depleting drug approved last year for the treatment of metastatic prostate cancer can help eliminate or nearly eliminate tumors in many patients with aggressive cancers that have yet to spread beyond the prostate, according to a clinical study to be presented at the annual meeting of the American Society of Clinical Oncology (ASCO), June 1-5, in Chicago.

The phase II clinical trial, led by investigators at Dana-Farber Cancer Institute and other research centers, examined the use of the drug abiraterone acetate (Zytiga(R)) in combination with prednisone and surgery in 58 men with high-risk prostate cancer isolated to the prostate gland. Participants received either three or six months of the two-drug regimen followed by surgery to remove the prostate. When the treatment was complete, pathology exams showed that one-third of the participants had no or almost no tumor tissue left.

"Very high-risk cancers localized to the prostate are rarely cured by prostatectomy alone," says the study's lead author, Mary-Ellen Taplin, MD, of Dana-Farber. "Therapies that combine surgery with older androgen-inhibiting drugs have not historically improved outcomes. This unmet need has given rise to efforts to develop new drugs capable of more completely reducing androgen levels within the prostate tumors."

Taplin will present the data (abstract 4521) on Saturday, June 2, at 8 a.m. CT, Arie Crown Theater, McCormick Place.

Androgen, the male hormone, provides the fuel for prostate cancer growth. Conventional therapies target androgen production in the testes and adrenal glands, but not within the tumor itself. Abiraterone acetate is capable of blocking androgen production in all three sites.

In the study, researchers used half the dose of prednisone (a steroid) standardly given with abiraterone acetate. This lower dose, it is hoped, would reduce the side effects associated with steroids while maintaining its benefits of protecting particular steroid imbalances associated with abiraterone. Since there were no increased side effects from abiraterone, the researchers feel that the lower dose of prednisone (5mg daily) is adequate for most patients.

"Most of the patients in this study had large tumors, high grade prostate cancers and were at high risk for cancer spread," Taplin remarks. "We're very encouraged by the results and have begun another phase II study investigating another novel androgen signaling inhibitor, MDV3100, in the neoadjuvant setting for high risk prostate cancer. We are also developing a clinical trial program investigating the addition of the investigational drug ARN509 to abiraterone. To prove the overall benefit of intensive androgen deprivation treatment in conjunction with prostatectomy, a large randomized clinical trial will need to be done."

Provided by Dana-Farber Cancer Institute