

Enzalutamide shows survival benefit in men with metastatic prostate cancer

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A combination of enzalutamide and androgen deprivation therapy (ADT) significantly reduced the risk of metastatic progression or death over time in men with advanced prostate cancer, according to the results

of clinical trial led by Duke Cancer Institute.

The findings, published in the *Journal of Clinical Oncology*, were the product of a multi-institutional study called ARCHES, which evaluated the efficacy and safety of enzalutamide, an androgen-receptor inhibitor, in conjunction with ADT.

The study enrolled 1,150 men with metastatic prostate cancer who had just begun treatment with [androgen deprivation therapy](#) or recently completed treatment with docetaxel and ADT; half of the men were randomly assigned to receive the [combination therapy](#); half received ADT and a placebo. Most of the men, 62 percent, had high volume disease, defined as having more than four metastatic sites in bone or spread to [internal organs](#), while 38 percent had low volume disease.

"Men who present with [metastatic prostate cancer](#) have a [poor prognosis](#) despite standard hormonal therapy and have a major unmet need," said lead author Andrew Armstrong, M.D., professor in the departments of Medicine and Surgery at Duke.

The study's primary end point was radiographic progression-free survival, and secondary endpoints include overall survival, time to castration resistance, time to further therapy, quality of life, time to skeletal events like fractures, and time to PSA progression.

Overall, enzalutamide plus ADT significantly reduced the risk of radiographic progression or death compared with placebo plus ADT by 61 percent. This improvement in disease progression was seen regardless of disease volume and prior therapy, including prior docetaxel use. Significant delays in skeletal related events, castration resistance, time to next therapy, and time to PSA progression were observed, with maintenance of a high quality of life over time.

"This data, combined with that of the several additional recently reported studies, suggest that more potent androgen receptor inhibition leads to better outcomes for our patients with [advanced prostate cancer](#)," Armstrong said. "Men now will have choices between several therapies, which is good news for our patients."

Armstrong said more data and follow-up will be needed to understand which patients benefit from combined ADT with docetaxel and enzalutamide (triple therapy) in terms of improved [overall survival](#), as compared with dual therapy with ADT and either docetaxel or enzalutamide.

More information: Andrew J. Armstrong et al. ARCHES: A Randomized, Phase III Study of Androgen Deprivation Therapy With Enzalutamide or Placebo in Men With Metastatic Hormone-Sensitive Prostate Cancer, *Journal of Clinical Oncology* (2019). [DOI: 10.1200/JCO.19.00799](#)

Provided by Duke University

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