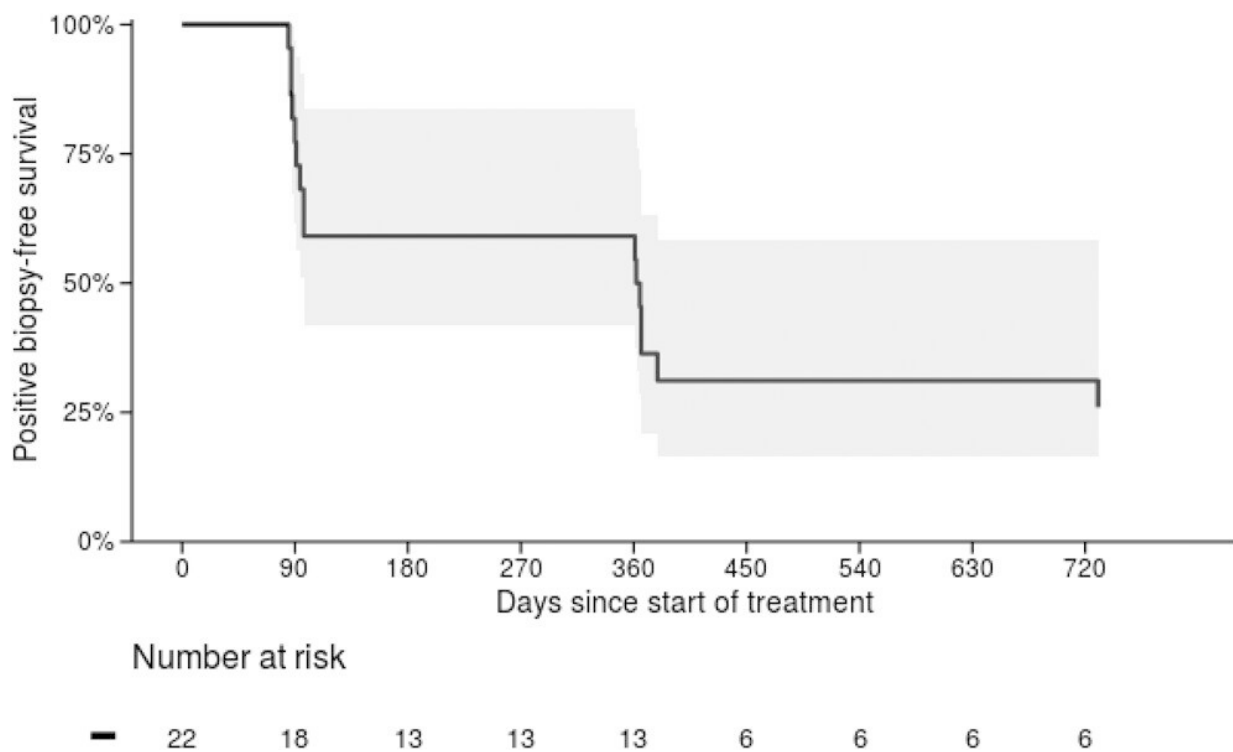


New hormonal agent may slow progression of early-stage prostate cancer during active surveillance

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Positive biopsy-free survival with 95% confidence limits (shaded gray areas).
 Credit: *Journal of Urology* (2023). DOI: 10.1097/JU.0000000000003038

For men with early-stage prostate cancer being managed by active surveillance, adding the hormonal agent apalutamide may lower the rate

of positive biopsies during follow-up, suggests a preliminary clinical trial in the *Journal of Urology*.

"In our study, 59% of men receiving 90 days of treatment with apalutamide had no evidence of residual [prostate cancer](#) on follow-up biopsy immediately posttreatment," comments lead author Michael T. Schweizer, MD, of University of Washington and Fred Hutchinson Cancer Center, Seattle. "Our preliminary findings support further studies to determine whether adding hormonal therapy might aid in reducing or preventing progression of early-stage prostate cancers during AS."

With apalutamide, initial biopsies are negative in most men on active surveillance

Active surveillance is a [treatment option](#) for some men with early-stage, slow-growing, "low-risk" or localized prostate cancer, potentially avoiding or delaying the need for definitive treatment, such as surgery or radiation.

Patients opting for [active surveillance](#) typically undergo regular prostate-specific antigen (PSA) screenings, prostate exams, imaging tests and repeat biopsies in order to carefully monitor prostate cancer growth or progression. Although active surveillance is increasingly regarded as a standard of care for men with low-risk prostate cancer, many patients eventually need further treatment.

Apalutamide is one of a class of potent novel hormonal agents approved for treatment of advanced prostate cancer. "Because of its antitumor effectiveness, apalutamide may also have the potential to control or shrink early forms of prostate cancer," Dr. Schweizer comments. "In addition, by avoiding reductions in testosterone levels, apalutamide may reduce sexual dysfunction and the many other side effects that can linger

after stopping conventional hormone therapies."

The preliminary (phase II) clinical trial investigated whether adding apalutamide to active surveillance for men with early-stage prostate cancer might affect the rate of cancer detection in follow-up biopsies. The study included 23 men, average age 67 years, who opted for active surveillance for initial treatment of low- to intermediate-risk prostate cancer. All patients received 90 days of oral apalutamide treatment, 240 milligrams per day

Fifty-nine percent of patients (13 of 22) who completed apalutamide treatment as planned had no evidence of residual cancer on immediate posttreatment biopsy. Upon long-term follow-up, rates of cancer-free biopsies were 33% at one year (seven of 21 patients) and 21% at two years (four of 19 patients).

Larger trials needed to assess hormonal agents' role in early-stage prostate cancers

In 65% of patients included in the study, PSA levels decreased by 90% or more with the addition of apalutamide. Five patients eventually underwent radiation or surgery for prostate cancer at a median of about two years.

In contrast to the effects of conventional hormonal therapies (i.e., LHRH agonists/antagonists), [testosterone levels](#) increased during apalutamide treatment, with a "minimal and transient" impact on quality of life. That's an important finding, because minimizing treatment impact on everyday functioning is a key reason why patients opt for active surveillance.

Dr. Schweizer and coauthors note that their small, preliminary trial did

not include a comparison group of men not receiving apalutamide. However, the immediate negative biopsy rate of 59% was higher than reported in previous studies of active surveillance. "Ultimately," the researchers write, "large randomized studies, designed to detect differences in clinically relevant endpoints will be needed to evaluate if systemic therapies are useful in the management of patients with [prostate cancer](#) followed on active surveillance."

More information: Michael T. Schweizer et al, Pathological Effects of Apalutamide in Lower-risk Prostate Cancer: Results From a Phase II Clinical Trial, *Journal of Urology* (2023). [DOI: 10.1097/JU.0000000000003038](#)

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