

Adding bicalutamide 150 mg to standard care for localised or locally advanced prostate cancer: results from the largest hormonal therapy trial ever conducted in prostate cancer patients, at over 7 years' follow up

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Background: The Early Prostate Cancer (EPC) programme is the largest treatment trial in patients (pts) with localised or locally advanced prostate cancer. The programme is helping to define which pts benefit, and which do not, from early or adjuvant antiandrogen therapy. Third analysis results, at 7.4 years' median follow-up, are presented.

Materials/Methods: The programme comprises 3 randomised, double-blind, placebo-controlled trials designed for combined analysis. Men (n=8113) with localised (T1–2, N0/Nx) or locally advanced (T3–4, any N; or any T, N+) prostate cancer (all M0) were recruited. Pts received bicalutamide 150 mg (n=4052) or placebo (n=4061) once daily plus standard care (radiotherapy [RT], radical prostatectomy [RP] or watchful waiting [WW]). Primary endpoints were overall survival (OS) and objective progression-free survival (PFS).

Results: In localised disease, no significant PFS or OS benefit was found with adding bicalutamide to standard care. In locally advanced disease, bicalutamide significantly improved objective PFS irrespective of standard care (WW, HR 0.60; RP, HR 0.75; RT, HR 0.56; $p < 0.001$ for all). Bicalutamide significantly improved OS in pts with locally advanced disease who received RT (HR 0.65; $p = 0.0276$); this was driven by a lower risk of death due to prostate cancer (16.1% vs 24.3%). Bicalutamide produced a trend towards improved OS in pts with locally advanced disease who would otherwise undergo WW (HR 0.81; $p = 0.057$). No OS difference was seen in RP pts.

Conclusions: The ongoing EPC programme provides clarity on the role of early or adjuvant antiandrogen therapy in pts with prostate cancer. Pts with localised disease do not appear to receive clinical benefit from bicalutamide. Pts with locally advanced disease derive significant clinical benefit from the addition of bicalutamide 150 mg to standard care; in particular, an OS benefit was seen in men who received RT.