

WEEKLY TAMOXIFEN
FOR GYNECOMASTIA

Weekly administration of prophylactic tamoxifen is much less effective than the standard daily regimen in preventing the adverse breast effects induced by bicalutamide.

Bicalutamide monotherapy is used to treat men with nonmetastatic prostate cancer who have opted out of androgen deprivation therapy. It is generally well-tolerated, but commonly induces gynecomastia and mastalgia. Bedognetti and colleagues investigated weekly administration as a potential means of reducing patient exposure and treatment costs.

Men with localized or recurrent prostate cancer were randomized to one of two treatment schedules. In the daily group, 41 participants received a 20 mg dose of tamoxifen each day. In the weekly group, tamoxifen at the same dose was administered once per week after an initial 8-week period of daily administration ($n=39$). Men in both cohorts were taking 150 mg of bicalutamide per day.

Enrollment for the nonblinded trial was halted prematurely when stark differences in the primary end point became evident, after a median of 24.2 months. Three-quarters of men in the weekly group developed ultrasound-detected gynecomastia, compared with one-third of those assigned to the daily regimen ($P<0.0001$). This difference emerged only after 6 months.

There was a similarly significant discrepancy in the incidence of questionnaire-assessed mastalgia; 46% and 12% in the weekly and daily groups, respectively. Weekly administration was also associated with more-severe breast symptoms. No between-group differences in sexual function or disease progression were observed.

Despite the long half-life of tamoxifen, switching to a weekly schedule significantly reduces its effectiveness against the main adverse effects induced by bicalutamide.

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Original article Bedognetti, D. *et al.* An open, randomised, multicentre, phase 3 trial comparing the efficacy of two tamoxifen schedules in preventing gynaecomastia induced by bicalutamide monotherapy in prostate cancer patients. *Eur. Urol.* 57, 238–245 (2010)