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Anastrozole versus tamoxifen for the prevention of locoregional and contralateral breast cancer in postmenopausal women with locally excised ductal carcinoma in situ (IBIS-II DCIS): a double-blind, randomised controlled trial.

Abstract:

Third-generation aromatase inhibitors are more effective than tamoxifen for preventing recurrence in postmenopausal women with hormone-receptor-positive invasive breast cancer. However, it is not known whether anastrozole is more effective than tamoxifen for women with hormone-receptor-positive ductal carcinoma in situ (DCIS). Here, we compare the efficacy of anastrozole with that of tamoxifen in postmenopausal women with hormone-receptor-positive DCIS. In a double-blind, multicentre, randomised placebo-controlled trial, we recruited women who had been diagnosed with locally excised, hormone-receptor-positive DCIS. Eligible women were randomly assigned in a 1:1 ratio by central computer allocation to receive 1 mg oral anastrozole or 20 mg oral tamoxifen every day for 5 years. Randomisation was stratified by major centre or hub and was done in blocks (six, eight, or ten). All trial personnel, participants, and clinicians were masked to treatment allocation and only the trial statistician had access to treatment allocation. The primary endpoint was all recurrence, including recurrent DCIS and new contralateral tumours. All analyses were done on a modified intention-to-treat basis (in all women who were randomised and did not revoke consent for their data to be included) and proportional hazard models were used to compute hazard ratios and corresponding confidence intervals. This trial is registered at the ISRCTN registry, number ISRCTN37546358. Between March 3, 2003, and Feb 8, 2012, we enrolled 2980 postmenopausal women from 236 centres in 14 countries and randomly assigned them to receive anastrozole (1449 analysed) or tamoxifen (1489 analysed). Median follow-up was 7.2 years (IQR 5.6-8.9), and 144 breast cancer recurrences were recorded. We noted no statistically significant difference in overall recurrence (67 recurrences for anastrozole vs 77 for tamoxifen; HR 0.89 [95% CI 0.64-1.23]). The non-inferiority of anastrozole was established (upper 95% CI <1.25), but its superiority to tamoxifen was not (p=0.49). A total of 69 deaths were recorded (33 for anastrozole vs 36 for tamoxifen; HR 0.93 [95% CI 0.58-1.50], p=0.78), and no specific cause was more common in one group than the other. The number of women reporting any adverse event was similar between anastrozole (1323 women, 91%) and tamoxifen (1379 women, 93%); the side-effect profiles of the two drugs differed, with more fractures, musculoskeletal events, hypercholesterolaemia, and strokes with anastrozole and more muscle spasm, gynaecological cancers and symptoms, vasomotor symptoms, and deep vein thromboses with tamoxifen. No clear efficacy differences were seen between the two treatments. Anastrozole offers another treatment option for postmenopausal women with hormone-receptor-positive DCIS, which may be more appropriate for some women with contraindications for tamoxifen. Longer follow-up will be necessary to fully evaluate treatment differences. Cancer Research UK, National Health and Medical Research Council Australia, Breast Cancer Research Fund, AstraZeneca, Sanofi Aventis.