

Adjuvant cytotoxic and endocrine therapy in pre- and postmenopausal patients with breast cancer and one to nine infiltrated nodes: five-year results of the Hellenic Cooperative Oncology Group randomized HE 10/92 study.

[Fountzilias G](#), [Stathopoulos G](#), [Kouvatseas G](#), [Polychronis A](#), [Klouvas G](#), [Samantas E](#), [Zamboglou N](#), [Kyriakou K](#), [Adamou A](#), [Pectasidis D](#), [Ekonomopoulos T](#), [Kalofonos HP](#), [Bafaloukos D](#), [Georgoulas V](#), [Razis E](#), [Koukouras D](#), [Zombolas V](#), [Kosmidis P](#), [Skarlos D](#), [Pavlidis N](#); [Hellenic Cooperative Oncology Group](#).

Source

1st Department of Internal Medicine, AHEPA Hospital, Aristotle University of Thessaloniki School of Medicine, Thessaloniki-Macedonia, Greece.

Abstract

SUMMARY: The present randomized phase III trial was designed to detect a 15% benefit in relapse-free survival (RFS) or overall survival (OS) from the incorporation of adjuvant tamoxifen to the combination of CNF [cyclophosphamide, 500 mg/m²; mitoxantrone (Novantrone), 10 mg/m²; fluorouracil, 500 mg/m² chemotherapy and ovarian ablation in premenopausal patients with node-positive breast cancer and conversely from the incorporation of CNF chemotherapy to adjuvant tamoxifen in node-positive postmenopausal patients. From April 1992 until March 1998, 456 patients with operable breast cancer and one to nine infiltrated axillary nodes entered the study. Premenopausal patients were treated with six cycles of CNF chemotherapy followed by ovarian ablation with monthly injections of triptoreline 3.75 mg for 1 year (Group A, 84 patients) or the same treatment followed by 5 years of tamoxifen (Group B, 92 patients). Postmenopausal patients received 5 years of tamoxifen (Group C, 145 patients) or 6 cycles of CNF followed by 5 years of tamoxifen (Group D, 135 patients). Adjuvant radiation was administered to all patients with partial mastectomy. After a median follow-up period of 5 years, 125 patients (27%) relapsed and 79 (17%) died. The 5-year actuarial RFS for premenopausal patients was 65% in Group A and 68% in Group B ($p = 0.86$) and for postmenopausal patients 70% in Group C and 67% in Group D ($p = 0.36$). Also, the respective OS rates were 77% and 80% ($p = 0.68$) for premenopausal and 84% and 78% ($p = 0.10$) for postmenopausal patients. Severe toxicities were infrequently seen, with the exception of leukopenia (18%), among the 311 patients treated with CNF. In conclusion, the present study failed to demonstrate a 15% difference in RFS in favor of node-positive premenopausal patients treated with an additional 5 years of tamoxifen after CNF adjuvant chemotherapy and ovarian ablation. Similarly, six cycles of CNF preceding 5 years of tamoxifen did not translate to a 15% RFS benefit in node-positive postmenopausal patients.