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Phase III trial (Prevention of Early Menopause Study [POEMS]-SWOG S0230) of LHRH analog during chemotherapy (CT) to reduce ovarian failure in early-stage, hormone receptor-negative breast cancer: An international Intergroup trial of SWOG, IBCSG, ECOG, and CALGB (Alliance).

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Abstract

LBA505

Background: Premature ovarian failure (POF) is a common toxicity of CT. Risk depends on type and amount of CT, age, and perhaps ovarian cycling at the time of CT. POEMS is a SWOG-coordinated phase III randomized study to evaluate whether LHRH analog administration with CT for early-stage breast cancer (BC) would reduce POF.

Methods: Premenopausal patients (PT) age <50 with stage I-IIIa ER/PR-negative BC to be treated with CT were randomized to receive standard cyclophosphamide-containing CT with or without monthly goserelin (GN) 3.6 mg SQ starting 1 week prior to the first CT dose. The primary endpoint is 2-year POF, defined as amenorrhea for the prior 6 months and post-menopausal FSH. Other endpoints include pregnancies and survival. Endpoints were analyzed in multivariable regression adjusting for stratification factors (age and CT regimen). **Results:** Between 2/04 and 5/11, 257 PT enrolled. Among 218 evaluable PT, 62% had complete primary endpoint data. Dropouts (n=83) were mostly due to deaths (n=14) or lack of FSH data. There was no strong evidence of informative missing data by arm according to stratification factors ($p>.05$). POF rates were 22% in the standard arm and 8% in the GN arm (OR=0.30, 95% CI: 0.10-0.87, $p=.03$ [unadjusted analysis]; OR=0.36, 95% CI: 0.11-1.14, $p=0.08$ [adjusted logistic regression analysis]). In a sensitivity analysis defining 2-year POF more liberally as either amenorrhea or elevated FSH, 45% in the standard arm and 20% in the GN arm had POF (OR=0.29, 95% CI: 0.12-0.70, $p=.006$). There were 13 pregnancies in the standard arm and 22 in the GN arm (OR=2.22, 95% CI: 1.00-4.92, $p=.05$). DFS and OS