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1: [J Natl Cancer Inst Monogr](#). 1994;(16):153-9.

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Randomized prospective trial of estrogen-replacement therapy in women with a history of breast cancer.

[Vassilopoulou-Sellin R](#), [Theriault RL](#).

Section of Endocrinology, University of Texas M.D. Anderson Cancer Center, Houston 77030.

With the onset of menopause, women develop increased risk for heart disease, vasomotor instability, and osteoporosis, which is related to estrogen deficiency, and can be corrected with estrogen-replacement therapy (ERT). Menopausal women with a history of breast cancer are advised against estrogen therapy because of concerns that ERT may adversely affect the course of the disease. There have been no prospective studies that address the issue of risk versus benefit for ERT in women with a history of breast cancer. We have initiated a randomized, prospective clinical study to define the influence, if any, of ERT on the clinical course of breast cancer (measure of potential risk) and the efficacy of ERT in the treatment of metabolic bone derangements (measure of benefit). Changes in serum lipids, cardiovascular events, and indices of psychological well-being are compared but do not constitute statistical end points. Eligible women must have had stage I or stage II breast cancer and must have had no evidence of disease for at least 2 years since therapy if estrogen-receptor-negative disease or for at least 10 years if the estrogen-receptor status is unknown. They were randomized to receive ERT (Premarin at 0.625 mg, days 1-25) versus no intervention (study control). Parameters of benefit and risk will be measured to detect a 10% change in disease-free rate for up to 5 years, with interim analyses at 20, 30, and 36 months of patient accrual. This study will allow us to begin the development of safe and effective strategies for the

management of estrogen deficiency in patients with breast cancer.(ABSTRACT TRUNCATED AT 250 WORDS)

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