

Prophylactic Use of Levonorgestrel-Releasing Intrauterine System in Women With Breast Cancer Treated With Tamoxifen: A Randomized Controlled Trial

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1. Discuss the effect of tamoxifen on the uterus of premenopausal and postmenopausal women. Review the risks for abnormal uterine bleeding, endometrial polyps, leiomyomas, and endometrial cancer and the methods of screening and diagnosis. [Practice Bulletin No. 126 from the American College of Obstetricians and Gynecologists](#) (“Management of gynecologic issues in women with breast cancer”; *Obstet Gynecol* 2012;119:666–82) is a useful resource for this review.
2. Review the [U.S. Medical Eligibility Criteria for Contraceptive Use, 2010](#), for the levonorgestrel-releasing intrauterine system. What category is assigned to the levonorgestrel-releasing intrauterine system use in current breast cancer? Discuss the evidence behind the classification.
3. Review the [Clinical Trial Registration](#). Note that the authors registered the trial with the Chinese Clinical Trial Registry and with the [Centre for Clinical Trials at the Chinese University of Hong Kong](#). Review the history of both registrations and compare with the conduct and analysis of the study as described in the paper. Discuss whether the study was performed as initially designed.
4. Discuss the method of randomization of treatment of study participants. Identify the methods of random sequence generation, blocking, and allocation concealment. Do these methods conform to the recommendations of the [CONsolidated Standards of Reporting Trials \(CONSORT\)](#) group?
5. Explore the ultrasonographic changes often seen in the uterus of women who are taking tamoxifen. Discuss the sensitivity of ultrasonography for identifying endometrial pathology. Discuss the potential effect of a levonorgestrel-releasing intrauterine device (IUD) in place on the sensitivity of ultrasonography for identifying endometrial pathology.
6. Imagine that you are counseling a woman with breast cancer who is about to start tamoxifen therapy. List the benefits and costs of the use of a levonorgestrel-releasing intrauterine system in this setting. What would be your recommendation to her?
7. Review [Practice Bulletin No. 121 from the American College of Obstetricians and Gynecologists](#) (“Long-acting reversible contraception: implants and intrauterine devices”; *Obstet Gynecol* 2011; 118:184–96). Discuss whether you agree or disagree with the statement that the levonorgestrel-releasing intrauterine system provides endometrial protection in women using tamoxifen as part of breast cancer therapy.