

If you would like to learn more about this study, please contact the study coordinators:

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TOP-END Study

(NWU 2017-09-01)

An opportunity to find new prevention approaches for women with DCIS and those at high risk of developing breast cancer



Pictured Above: medicated gel container with hand pump



Why Is This Study Being Done?

- Many women hesitate to take breast cancer prevention medication for fear of side effects.
- You can help us test a different, possibly safer way of taking medications for breast cancer prevention: by applying them to the breast skin. We hope that this way of taking medication will greatly reduce the drug dose to the rest of the body, and therefore decrease side-effects of drugs taken for prevention of breast cancer.
- This study will test the safety of a new medicated gel containing endoxifen (an active form of tamoxifen) applied to the breast skin at different doses. We want to find out if the gel causes any skin irritation (other similar gels do not) and if the medication reaches the breast.

What Are the Study Groups?

- Group 1: apply endoxifen gel (5 mg per breast) or placebo gel to both breasts daily until the day before surgery
- Group 2: apply endoxifen gel (10 mg per breast) or placebo gel to both breasts daily until the day before surgery
- Group 3: apply endoxifen gel to both breasts daily at the safest/best dose determined by Groups 1 and 2 but stop 3 days before surgery

You May be Eligible If You:

- Are a woman planning surgery to remove one or both breasts for stage 0-III breast cancer treatment or for breast cancer prevention.
- Not currently pregnant or breastfeeding
- Have no history of uterine cancer or blood clots

If you take part in this study, you will be asked to do the following:

- Attend 3 - 4 study appointments
- Apply a topical gel to both breasts daily for 3 - 4 weeks before surgery
- Have blood drawn and complete questionnaires at the start and end of the study
- Have a weekly progress phone call
- Complete breast skin assessment at each study visit

