

The PROMISE Trial: A large-scale multicenter phase II study evaluating the protective effect of a tissue selective estrogen complex (TSEC) in women with newly diagnosed ductal carcinoma in situ

Why is this study being done?

The purpose of this study is to determine if taking the study drug, Duavee, causes any changes in the breast tissue of women with DCIS that may reduce the risk of developing invasive breast cancer.

The study drug is approved by the US Food and Drug Administration for healthy postmenopausal women to treat certain symptoms of menopause such as hot flashes. Since it is not approved in women with DCIS, its use in this study is investigational.

Who can participate in this study?

You may be eligible for this study if you:

- Are between the ages of 18 and 79
- Are postmenopausal
- Have newly diagnosed ER (+) DCIS and are planning to have surgical therapy
- Have never had invasive breast cancer

What will happen if you join the study?

If you join the study, you will be asked to:

- Have blood drawn for testing and research;
- Take study pill or placebo tablets daily for about 28 days leading up to your surgery;
- Allow the research team to access to your medical records;
- Fill out a drug diary and 2 questionnaires at the beginning and on the day of surgery;
- Allow the research team to obtain tissue samples from your biopsy and surgery;
- Have phone calls with the study team to check on progress and talk about symptoms.

How long is the study?

The entire study treatment cycle lasts 21-35 days depending on when your surgery is scheduled, during which time you will be taking the study drug or placebo once per day. You will then be asked to come in about 2 weeks after your surgery for a final visit.

How do I get more information?

If you wish to participate or learn more about the study, please contact:

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