

INT23-14-01 REFINING TAMOXIFEN DOSE FOR PREMENOPAUSAL BREAST CANCER RISK REDUCTION (RENAISSANCE)

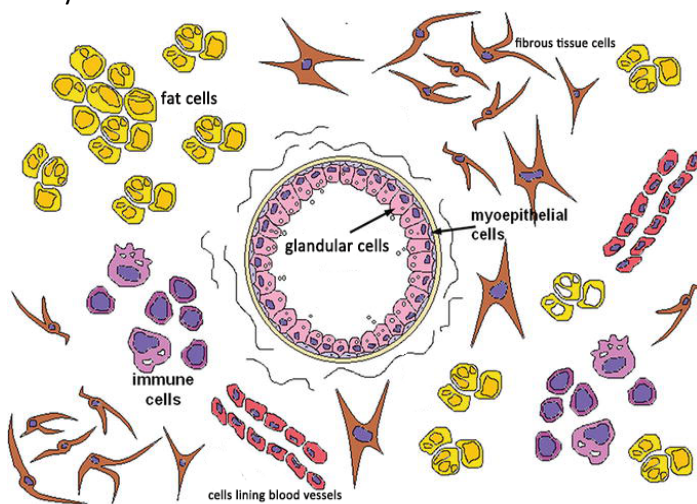


- **Thank you for considering the RENAISSANCE trial!**

- We are asking you to also consider doing **two needle biopsies** of the breast as you go through the trial, one biopsy would occur before starting low-dose tamoxifen and the other six months later. This is **optional**, but if you agree, you will greatly increase the knowledge you will contribute from your participation.

- **Why do clinical trials often include research biopsies?**

- When we test a new approach to treatment, we must have a good way of measuring the effects of the new method. This can be done with blood tests or X-rays, and both of these give us good information. But the type of information that we can get from a biopsy is very different.
- **With a biopsy sample, we can see how cells change with treatment, and why the treatment is working in some people, and not in others.** In this study, where we are measuring changes in breast density, looking at a biopsy sample will show us how different cell types in the breast talk to each other in women whose breast density changes, and in women whose density does not change.
- Through this kind of understanding, we can find ways to improve the results of treatment for women who do not appear to be benefiting from current treatment.
- Looking at breast cells directly through biopsy is the closest we can come to watching the drug at work in the breast and how to make the drug work better.



The breast is made up of many different cells with different functions. In a biopsy sample we can see exactly which cell type is responding to tamoxifen when breast density changes and when it does not. This will help us develop prevention approaches that work for all women.

- **What will I experience if I agree to the needle biopsy?**

- This biopsy is easier than a breast needle biopsy you may have had in the past because of an abnormal mammogram. It is much quicker, you do not have to lie in an uncomfortable position, the likelihood of pain or significant bruising is far less.
- You will lie on your back with your arm above your head; a doctor will use an ultrasound to find the dense tissue in your breast, then give you numbing medicine in this area. A nick in your numbed skin about the size of a hyphen (-) will be made, and then a needle will be inserted to remove a few samples of breast tissue (about the thickness of a pencil lead).
- **This is a quick procedure which should not take longer than 10 minutes.**
- The collected tissue will be studied under a microscope using special methods which tell us about the dense portion of your breast tissue.



- **What are the risks?**

- You will feel the injection of the numbing medicine (like a bee sting). Once the area is numb, you may feel some pressure as the biopsy needle is introduced, but usually minimal or no pain. The scar is the size of a hyphen (-) and usually becomes invisible in a few months. There will likely be a mild bruise at the biopsy site which may take a few days to resolve.
- The chance of developing a major bruise or lump is less than 1 in 100 women; it is lower than needle biopsies that are done to diagnose abnormalities since we will be sampling normal breast tissue.

For more information or if you have any questions, please contact ncpc@northwestern.edu.



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