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

FREQUENTLY ASKED QUESTIONS (FAQs):

What is Tamoxifen and how does it work?

Tamoxifen is a medication that blocks estrogen from reaching breast cells. Estrogen is linked to breast cancer growth and blocking it with Tamoxifen is proven to reduce breast cancer risk in premenopausal women. It also reduces breast density, and studies show that reduction in breast density leads to a lowering of breast cancer risk.

Why is breast density important? Dense breast tissue can reduce the effectiveness of mammograms for breast cancer detection since cancers can hide in dense breast tissue. And women with dense breasts are at increased risk of developing breast cancer.

What is the usual dose of tamoxifen?

The standard dose for Tamoxifen is 20 mg daily, often recommended to women at double or higher risk of breast cancer. While this dose of Tamoxifen is effective in reducing breast cancer risk, some side effects discourage women from taking it.

Are there alternative dosages of tamoxifen available?

A recent study suggests that a smaller dose of tamoxifen, around 5 mg daily, can reduce breast cancer risk with fewer side effects compared to the usual 20 mg dosage, but 5 mg may not be enough for all premenopausal women.

What is the purpose of this study?

The purpose of this study is to determine whether dosing of Tamoxifen can be personalized for each premenopausal woman based on the decrease in breast density measured on mammograms. We will use a precise method to measure breast density rather than what the radiologist estimates in the usual mammogram report. This means that we can use each woman's breast density changes to give her the right amount of Tamoxifen.

How can the right tamoxifen dosage be determined? What does participation involve?

Participants will undergo an initial mammogram and breast density will be measured, then start a 6-month course of low-dose Tamoxifen (5 mg/day). Women whose density decreases on follow-up mammogram can remain on the 5 mg dose (we expect this will be true for 70% of the participants). If density does not decrease sufficiently, the Tamoxifen dose will increase to 10 mg. If no density decreases on this dose, the standard 20 mg dose will be needed. Additionally, participants will have physical exams, blood draws, and complete questionnaires.

Who can participate in the study?

Women between the ages of 18 and 55 who have not reached menopause, are at higher-than-average risk of breast cancer, have no history of invasive breast cancer, and are not pregnant or breastfeeding may be eligible to participate.

How long is the study period?

The entire period of study participation is 18 months during which there will be four study visits. After this period, you may choose to continue the dose of tamoxifen you are on.

Will participants be compensated to participate?

Compensation will be provided to cover your transportation, parking, and other study-related time and expenses.

How many participants will be enrolled in the study? How can I join the study?

The study aims to enroll 200 women at ten institutions across the country. If you think you may be eligible or have any further questions, please contact ncpc@northwestern.edu.

Northwestern University
Carbone Cancer Center
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH
ROGEL CANCER CENTER
MICHIGAN MEDICINE
NCI Cancer Prevention Clinical Trials Network
A program of the National Cancer Institute of the National Institutes of Health
THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
MUSC Medical University of South Carolina
Hollings Cancer Center
An NCI-Designated Cancer Center
THE UNIVERSITY OF ARIZONA Cancer Center
THE UNIVERSITY OF KANSAS CANCER CENTER
Dana-Farber Cancer Institute
Brigham Cancer Center
University Hospitals
UI Health
UNIVERSITY OF ILLINOIS CANCER CENTER
Washington University in St. Louis
SCHOOL OF MEDICINE