The OFSET Study: Testing the addition of chemotherapy to the usual treatment of ovarian function suppression plus hormonal therapy in premenopausal ER-positive/HER2-negative breast cancer patients who are at high risk of cancer returning.

NRG ONCOLOGY

Advancing Research. Improving Lives.™

Visit the patient webpage for this study:

ABOUT THE TRIAL

NRG-BR009: The OFSET Study

A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score ≤ 25 (OFSET)

NRG-BR009 is a clinical trial being done to answer the following question:

Will the chance of your breast cancer returning be less if chemotherapy is added to hormonal therapy with an aromatase inhibitor and ovarian suppression? We are doing this study because we want to find out if this approach is better or worse as the other usual approach for your early-stage breast cancer that is sensitive to hormones, is HER2-negative, and is at higher risk for cancer returning. The usual approach is defined as care most premenopausal people get for early-stage breast cancer that is sensitive to hormones, is HER2-negative, and is at higher risk for cancer returning.

ClinicalTrials.gov Identifier: NCT05879926

ABOUT NRG ONCOLOGY

As one of the five research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on sex-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI. To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org.

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Frequently Asked Questions

What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
Premenopausal women who have early-stage breast cancer that is sensitive to hormones and is HER2-negative, and an Oncotype DX Recurrence Score® equal to or less than 25.

Am I required to be in this study?
No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the possible treatments & how long will I be in this study?
If you decide to take part in this study, you will either get an ovarian suppression drug with hormonal therapy for up to 5 years, or you will get chemotherapy and then an ovarian suppression drug with hormonal therapy for up to 5 years.

After you finish your study treatment or if you stop your study treatment early, your doctor and study team will watch you for side effects. They will check you every 12 months until 15 years after you joined the study.

If you decide to take part in this study and you are a patient with a MammaPrint Low Risk or MP1 result and you do not have an Oncotype DX Recurrence score, some of the tissue left over from your primary breast tumor when you were diagnosed with cancer will be sent to have an Oncotype DX Recurrence score done. If the test shows that your Oncotype DX Recurrence Score is equal to or less than 25 and you meet all other study requirements, you can join the study.

Are there side effects?
There may be some. The most common side effects from chemotherapy that study doctors know about are tiredness, infection, bruising/bleeding, anemia, hair loss, nausea/vomiting, diarrhea, swelling of the arms and legs, numbness/tingling or pain of the arms and legs, absence of menstrual period which may decrease the ability to have children, hot flashes/flushing, and increased sweating.

There may be some side effects from ovarian suppression including hot flashes/flushing, increased sweating, depression/mood swings, headache, pain, and absence of menstrual period which may decrease the ability to have children.

There may be some side effects from hormonal therapy that study doctors know about including hot flashes/flushing, increased sweating, aching or pain in the joints, vaginal dryness, tiredness, and depression/mood swings.

There may be some risks that the study doctors do not yet know about; however, your doctor will review all of the potential known side effects with you.

MORE INFORMATION

Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer.
You may also call: 1-(800)-4-CANCER (1-800-422-6237).