



Cynthia X. Ma, MD, PhD

“Successful completion of the ALTERNATE study, including in-depth analyses of blood and tumor samples collected during the trial, will allow us to identify which people can avoid chemotherapy and to identify drivers of treatment resistance so new drugs can be designed.”

-Cynthia X. Ma, MD, PhD

## Alternate Hormone Therapy Approaches for Invasive Estrogen Receptor-Positive Breast Cancer

**STUDY TITLE:** Alternate Approaches for Clinical Stage II or III Estrogen Receptor Positive Breast Cancer Neoadjuvant Treatment (ALTERNATE) in Postmenopausal Women: A Phase III Study

**TRIAL NUMBER:** NCT01953588

**FOCUS:** Treatment

**TRIAL PHASE:** [Phase III \(Phase 3\)](#)

### WHAT HAPPENS IN THIS STUDY?

Fulvestrant is a type of [hormone therapy](#) (also called endocrine therapy) that works by blocking and reducing the number of estrogen receptors (ERs) in cancer cells and is used to treat metastatic ER-positive (ER+) breast cancer. Anastrozole is another type of hormone therapy that works by reducing estrogen levels and is used to treat early or locally advanced (stage II-III) ER+ breast cancer to prevent recurrence in postmenopausal women. The goal of this study is to determine whether treatment with fulvestrant or the combination of anastrozole and fulvestrant before surgery will improve outcomes and decrease treatment resistance for people with stage II-III ER+ breast cancer when compared to anastrozole alone, so that some patients can avoid chemotherapy after surgery. Patients enrolled in this study are being followed for 10 years to determine whether those who did not get chemotherapy have a very low risk of recurrence.

This is a randomized trial, which means neither the doctor nor the participant chooses the study group for a patient. Instead, participants are assigned by chance to receive either fulvestrant, anastrozole, or fulvestrant and anastrozole.

### ARE YOU ELIGIBLE?

This study is active but no longer enrolling new participants. The status of this study is subject to change. To see the most up-to-date information, visit [clinicaltrials.gov](https://clinicaltrials.gov).

### WHAT WILL THIS MEAN FOR PATIENTS?

This study offers participants the chance to receive different therapies for ER+ breast cancer that has not spread to distant sites. It will help researchers and doctors learn which hormone therapies work better to stop this type of breast cancer from growing prior to surgery so chemotherapy can be avoided after surgery. Participants will contribute to cancer research that one day may help improve outcomes for ER+ breast cancer by preventing resistance and recurrence.

### WHO DO I CONTACT ABOUT THIS STUDY?

#### STUDY CHAIR AND TRIAL SPONSOR:

- Cynthia X. Ma, MD, PhD, Washington University in St. Louis, St. Louis, Missouri, United States.
- Alliance for Clinical Trials in Oncology, Chicago, Illinois, United States.

#### STUDY LOCATIONS:

This study was offered at multiple [locations](#) across the country.

### KOMEN CONNECTION

Cynthia X. Ma, MD, PhD, the Study Chair of this trial, is a [Komen Scholar](#) from Washington University in St. Louis. She is a leading expert on ER+ breast cancer. Komen is supporting correlative studies led by Dr. Ma to develop unique biomarkers that define endocrine therapy resistance from patient samples collected during this clinical trial.

### SUSAN G. KOMEN BREAST CARE HELPLINE

*Do you need help? We're here for you.* The [Komen Patient Care Center](#) is your trusted, go-to source for timely, accurate breast health and breast cancer information, services and resources. Our navigators offer free, personalized support to patients, caregivers and family members, including education, emotional support, financial assistance, help accessing care, information on clinical trials and more. Get connected to a Komen navigator by contacting the Breast Care Helpline at 1-877-465-6636 or email [helpline@komen.org](mailto:helpline@komen.org) to get started. All calls are answered Monday through Friday from 9:00 a.m. to 10 p.m. ET. Se habla español.



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