



ELEGANT

TRIAL TITLE

A Study of Elacestrant Versus Standard Endocrine Therapy in Women and Men With ER+, HER2-, Early Breast Cancer With High Risk of Recurrence (ELEGANT)

TRIAL STATUS

Recruiting

TRIAL NUMBER

[NCT06492616](https://clinicaltrials.gov/ct2/show/study/NCT06492616)

TRIAL PHASE

Phase 3

PARTICIPANTS ELIGIBLE FOR THE STUDY*:

- You are a woman or man aged 18 years or older.
- You have been diagnosed with ER-positive/HER2-negative early-stage breast cancer that has spread to the nearby lymph nodes.
- You had surgery to remove the tumor 2-6 years ago.
- You have received between 2-5 years of hormone therapy for breast cancer with or without a CDK4/6 inhibitor (abemaciclib or ribociclib).

*This is not a complete list of eligibility criteria for the clinical trial. Other inclusion or exclusion criteria may apply.

Spotlight on Clinical Trials

FACT SHEET

TRIAL DETAILS:

- ELEGANT is a global, multicenter, [randomized](#), [open-label](#), [phase 3 clinical trial](#) across 500+ sites in 28 countries.
- This study aims to enroll approximately 4,220 participants.
- The goal of the study is to see whether elacestrant is more effective compared with standard hormone therapy in patients with node positive early-stage breast cancer with a high risk of recurrence.
- Participants will receive either elacestrant or the same standard hormone therapy they were receiving before joining the study (anastrozole, letrozole, exemestane, or tamoxifen).
- Participants either start elacestrant once daily (345 mg) or continue their prior standard hormone therapy, with treatment planned for up to 5 years.

ABOUT ER+/HER2- EARLY BREAST CANCER AND ELACESTRANT:

- ER+, HER2- early breast cancer is the most common type of breast cancer and usually responds well to hormone-blocking treatments such as tamoxifen or aromatase inhibitors.
- While patients do very well with current treatments, breast cancer can still come back (recurrence). This is why new treatment options are being studied to lower the risk of cancer returning.
- Elacestrant is a treatment designed to block and break down the estrogen receptors in cancer cells, inhibiting their growth. Elacestrant can potentially avoid the spread of breast cancer while reducing hot flashes and protecting bone health.
- Elacestrant (brand name: Orserdu) is an oral selective estrogen receptor degrader (SERD) FDA-approved to treat ER+, HER2- metastatic breast cancer in postmenopausal women with ESR1 tumor gene mutation who were treated with hormone therapy in the metastatic setting.
- Elacestrant is being studied to treat ER+ early breast cancers.
- Side effects of elacestrant include: nausea, vomiting, fatigue, decreased appetite, muscle and joint pain, diarrhea, back pain, headache, constipation, hot flashes, and potentially increased cholesterol levels (which will be checked before enrollment and regularly while taking the drug).
- The ELEGANT study is open to people of all gender identities, ethnicities and racial backgrounds.



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Spotlight on Clinical Trials

FACT SHEET

References:

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2. Susan G. Komen. Tumor Characteristics, Susan G. Komen, Accessed January 2026. <https://www.komen.org/breast-cancer/diagnosis/factors-that-affect-prognosis/tumor-characteristics>
3. Stemline Therapeutics, Inc. A Study of Elacestrant Versus Standard Endocrine Therapy in Women and Men With ER+, HER2-, Early Breast Cancer With High Risk of Recurrence (ELEGANT). <https://clinicaltrials.gov/study/NCT06492616#study-overview>
4. Bardia et al. ELEGANT: Elacestrant versus standard endocrine therapy (ET) in women and men with node-positive, estrogen receptor-positive (ER+), HER2-negative (HER2-), early breast cancer (eBC) with high risk of recurrence in a global, multicenter, randomized, open-label phase 3 study. J Clin Oncol. 2025. DOI: 10.1200/JCO.2025.43.16_suppl.TPS619
5. Susan G. Komen. Selective Estrogen Receptor Degraders (SERDs) for Metastatic Breast Cancer, Susan G. Komen, Accessed January 2026. <https://www.komen.org/breast-cancer/metastatic/metastatic/serds-for-metastatic-breast-cancer>
6. Estrogen-dependent cancers: Causes, diagnosis & treatment. Cleveland Clinic, Accessed December 10, 2024. <https://my.clevelandclinic.org/health/diseases/10312-estrogen-dependent-cancers>
7. Bidard FC, et al. J Clin Oncol. 2022;40(28):3246-3256.

Clinical trials can be confusing. To learn more about them and some common terms check out this [page](#).



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