

E1Z11 Clinical Trial Results Summary

A Study to Evaluate Genetic Predictors of Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)

What did this trial involve and who was it for?

E1Z11 was for people with stage 1–3 breast cancer who were prescribed anastrozole, a type of hormone therapy called an aromatase inhibitor. Aromatase inhibitors lower the amount of estrogen in the body. Because estrogen can help some breast cancers grow, lowering estrogen may help slow or stop that growth. Muscle and joint aches or pain are common side effects of this medication, but researchers do not fully understand why they happen. For some patients, these side effects can be severe enough that they choose to stop the medication.

Previous research has suggested that a person's genetic makeup may help predict whether they will develop muscle and joint pain while taking an aromatase inhibitor. The purpose of E1Z11 was to see whether 10 alterations in specific genes could help predict which patients taking anastrozole were most likely to experience these side effects and stop taking the medication.

From May 2013 to October 2018, 970 women from different population groups nationwide enrolled in E1Z11. All study participants received the same treatment: 1 mg of anastrozole once a day for 12 months. After 12 months, participants could continue taking anastrozole if their doctor recommended it. They could also stop taking the medication if their doctor determined that side effects had become too severe.

Participants completed surveys at the start of the study and again at 3, 6, 9, and 12 months. The surveys asked about side effects, quality of life, and concerns about the cancer coming back. Afterward, participants continued to be followed by their doctor for 5 years from the time they joined the study.

What are the results?

- Overall, 43% of participants reported muscle and joint aches and pains, and 12% stopped taking their aromatase inhibitor within 12 months.
 - Although more Black women (49%) and Asian women (50%) experienced these side effects than White women (39%), the percentage of patients who stopped treatment was similar across all of the groups.
- Researchers found that none of the 10 alterations in the specific genes studied could predict which patients would develop muscle and joint pain. This was true both overall and across different population groups.

What do the results mean for patients?

- While the specific alterations and genes studied in E1Z11 were not linked to muscle and joint pain or treatment discontinuation, the results are helping researchers identify new directions for future studies.
- Likewise, the patient survey responses are helping researchers better understand patients' experiences with taking aromatase inhibitors and how to best support them during treatment.

For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine:
<https://clinicaltrials.gov/study/NCT01824836>
 - *Clinical Cancer Research* (2024): <https://pmc.ncbi.nlm.nih.gov/articles/PMC11287923/>
 - *Journal of Clinical Oncology* (2021):
https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.12003
-

About ECOG-ACRIN

This trial was led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN). ECOG-ACRIN is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN is a component of the National Cancer Institute's National Clinical Trials Network. Learn more at www.ecog-acrin.org.

To all the patients that participated in this trial, thank you. Your participation, and that of other patients like you, made this research possible.