



OASIS-4

TRIAL TITLE

A Study to Learn More About How Well Elinzanetant Works and How Safe it is Compared to Placebo for the Treatment of Hot Flashes Caused by Anti-cancer Therapy in Women With, or at High Risk for Developing Hormone-receptor Positive Breast Cancer (OASIS-4)

TRIAL STATUS

Active, not recruiting

TRIAL NUMBER

[NCT05587296](https://clinicaltrials.gov/study/NCT05587296)

TRIAL PHASE

Phase 3

PARTICIPANTS ELIGIBLE FOR THE STUDY*:

- Women aged 18-70 who are having hot flashes caused by hormone therapy (such as tamoxifen or aromatase inhibitors)
- History of hormone-receptor positive (HR+) breast cancer (not metastatic or recurrence) or who are at high risk for developing breast cancer
- No other cancers other than HR+ breast cancer or basal/squamous cell skin cancer
- No breast cancer treatment (surgery or other) or breast cancer within 3 months before signing informed consent (except hormone therapy)
- No unexplained vaginal bleeding

*Additional eligibility criteria may apply.

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



Spotlight on Clinical Trials

FACT SHEET

TRIAL DETAILS:

- Hormone therapy is an effective treatment for HR+ breast cancer, but it often causes hot flashes which can impact quality of life and sometimes lead to someone stopping treatment early.
- Elinzanetant is FDA-approved to treat menopausal hot flashes and is being studied in the OASIS-4 trial for hot flashes related to hormone therapy in people with HR+ breast cancer.
- The goal of the OASIS-4 study is to find out how well elinzanetant helps to treat hot flashes caused by hormone therapy in women with or at high risk for developing HR+ breast cancer compared to placebo.
- Participants from multiple trial locations (multicenter) will be randomly assigned to one of two groups. Neither the participants nor researchers know who's in which group (double blind).
 - Group A: Take elinzanetant once a day for 52 weeks, or
 - Group B: Take a placebo once a day for 12 weeks, followed by elinzanetant for the remaining 40 weeks
- Participants will use an electronic diary to record information about their hot flashes and symptoms before starting the study and at various times during the study.
- All participants will continue the hormone therapy they were taking at the time of enrollment.
- Study participation lasts about 62 weeks and includes up to 12 study visits and 6 phone calls.
- Participants who complete 52 weeks of treatment may be offered the option to continue elinzanetant in a longer-term extension phase.

ABOUT HORMONE THERAPY, HOT FLASHES AND ELINZANETANT:

- Hot flashes and night sweats are common side effects of hormone therapy for HR+ breast cancer.
- These symptoms can disrupt sleep, daily activities and overall quality of life, and may make it harder for some people to remain on hormone therapy.
- Treatment options for menopause are limited because hormone-based therapies are not recommended for many people with a history of breast cancer. This is because estrogen can stimulate HR+ breast cancer cells and may increase the risk of cancer growth or recurrence, even after treatment has been completed.
- Elinzanetant is a non-hormonal pill that works by blocking certain signals in the brain believed to cause hot flashes.
- Elinzanetant does not contain estrogen and does not act on estrogen receptors, making it a potential option for people with HR+ breast cancer.

References:

1. Susan G. Komen. Treating menopausal symptoms in women who've had breast cancer, Susan G. Komen, Accessed May 2026. <https://www.komen.org/wp-content/uploads/Treating-Menopausal-Symptoms.pdf>
2. Susan G. Komen. Managing Menopause- Komen Perspectives, Susan G. Komen, Accessed May 2026. <https://www.komen.org/blog/komen-perspectives-managing-menopause/>
3. Bayer. A Study to Learn More About How Well Elinzanetant Works and How Safe it is Compared to Placebo for the Treatment of Hot Flashes Caused by Anti-cancer Therapy in Women With, or at High Risk for Developing Hormone-receptor Positive Breast Cancer (OASIS-4). <https://clinicaltrials.gov/study/NCT05587296#study-overview>
4. Cardoso et al. Elinzanetant for vasomotor symptoms from endocrine therapy for breast cancer. *N Engl J Med*. 2025. DOI: 10.1056/NEJMoa2415566