



OPERA-01

TRIAL TITLE

OP-1250 (Palazestrant) vs. Standard of Care for the Treatment of ER+/HER2-Advanced Breast Cancer (OPERA-01)

TRIAL STATUS

Recruiting

TRIAL NUMBER

[NCT06016738](https://clinicaltrials.gov/ct2/show/study/NCT06016738)

TRIAL PHASE

Phase 3

PARTICIPANTS ELIGIBLE FOR THE STUDY*:

- Adult male or female diagnosed with ER-positive/HER2-negative advanced or metastatic breast cancer that has progressed after prior hormone therapy.
- Female participants may be pre-, peri-, or postmenopausal.
- Participants must have previously received a CDK4/6 inhibitor (such as ribociclib, palbociclib or abemaciclib) combined with hormone therapy.
- Participants must not have received chemotherapy for advanced and/or metastatic breast cancer.

*Additional eligibility criteria may apply



Spotlight on Clinical Trials FACT SHEET

TRIAL DETAILS:

- Approximately 510 participants will be randomized to receive palazestrant or the physician's choice of standard-of-care hormone therapy, which could be fulvestrant, anastrozole, letrozole or exemestane.
- Palazestrant is a pill that is taken once daily.
- Fulvestrant is an injection that is injected into the muscle twice a month for the first month, then once a month thereafter. Anastrozole, letrozole and exemestane are pills taken once daily.
- Researchers will determine if palazestrant delays breast cancer progression and prolongs lives better than the physician's choice of hormone therapy.

ABOUT METASTATIC ER-POSITIVE BREAST CANCER AND PALAZESTRANT:

- People with ER-positive breast cancer that has spread to other parts of the body (metastatic) are treated with [hormone therapy](#) in combination with a CDK4/6 inhibitor. Once this treatment stops working, they can switch to a different hormone therapy, and potentially other targeted treatments depending on their cancer characteristics.¹
- Eventually, after all hormone therapy treatments are exhausted, [chemotherapy](#) is used.¹
- More treatment options are needed for people with metastatic ER-positive breast cancer.
- Palazestrant is being tested as a new hormone therapy option for people with metastatic ER-positive breast cancer.
- An earlier clinical trial found that palazestrant resulted in a clinical benefit rate of 40% and led to a median progression-free survival of 4.6 months for people with metastatic ER-positive breast cancer that was previously treated and progressed on or returned after other treatments.²

REFERENCES:

1. Hormone Therapy for Metastatic Breast Cancer: <https://www.komen.org/breast-cancer/metastatic/metastatic/hormone-therapy-for-metastatic-breast-cancer/>
2. Lin NU et al. Results from the phase 1/2 study of OP-1250, an oral complete estrogen receptor (ER) antagonist (CERAN) and selective ER degrader (SERD) in patients (pts) with advanced metastatic ER-positive, HER2-negative breast cancer. 2023 European Society for Medical Oncology (ESMO) Congress 2023, Madrid, Spain, October 22, 2023.