

TRADE

TRIAL TITLE

TRADE: Dose Escalation Tolerability of Abemaciclib in HR+ HER2- Early Stage Breast Cancer

TRIAL STATUS

Active, not recruiting

TRIAL NUMBER

[NCT06001762](https://clinicaltrials.gov/ct2/show/NCT06001762)

TRIAL PHASE

Phase 2

PARTICIPANTS INCLUDED IN THE STUDY*:

- Adults (women and men) diagnosed with stage II or III, node-positive, HR-positive/HER2-negative early breast cancer who were candidates for abemaciclib and hormone therapy after surgery.
- Participants had to have had breast cancer surgery within 16 months of enrolling and recovered from chemotherapy (at least 21 days since the last dose), radiation therapy (at least 14 days since completion) and from prior breast surgery (at least 14 days).
- No prior CDK4/6 inhibitor.
- Individuals were never diagnosed with inflammatory breast cancer.
- No history of prior invasive breast cancer unless disease-free for 5 or more years.

*Additional eligibility criteria may have applied.

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



Breast Cancer Breakthroughs

FACT SHEET

TRIAL DETAILS:

- TRADE is a prospective, single-arm, open-label, phase 2 clinical trial.
- 90 participants enrolled.
- Treatment included adjuvant abemaciclib plus hormone therapy after surgery and other standard treatments.
- The study is testing whether starting abemaciclib at a lower dose and gradually increasing the dose would be easier to tolerate than starting at the full dose immediately.
- Participants started abemaciclib at 50 mg twice daily for two weeks, then increased to the full dose of 150 mg twice daily at the start of month two.
- Treatment cycles were 28 days, and abemaciclib was given for two years.

ABOUT HR+/HER2- BREAST CANCER AND ABEMACICLIB:

- HR+/HER2- early breast cancer is the most common breast cancer and often responds well to hormone therapy (e.g. tamoxifen, aromatase inhibitor).
- Many patients achieve positive outcomes, but there is risk of breast cancer returning, also known as recurrence. Additional treatment approaches are needed to prevent recurrence.
- CDK4/6 inhibitors (abemaciclib and ribociclib) are sometimes used in combination with hormone therapy for people with early HR+, HER2- breast cancer that are at a higher risk of recurrence.
- Abemaciclib is a CDK4/6 inhibitor FDA-approved to reduce recurrence risk when added to hormone therapy and has now demonstrated the ability to help patients live longer.
- Side effects of abemaciclib can occasionally lead to dose reductions or stopping treatment.
- Results from the TRADE trial have shown that 70.8% of patients reached and maintained the target dose of abemaciclib (150 mg twice daily) at 12 weeks.
- Early discontinuation was low with only 6.7% of patients stopping treatment before week 12; 9% never reached the full dose; 13.5% required dose reductions from the full dose by week 12.
- The gradual “start low, go slow” dosing approach was better tolerated compared with historical reports of starting at full dose, making abemaciclib treatment more manageable.

References:

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4. Dana-Farber Cancer Institute. TRADE: Dose Escalation Tolerability of Abemaciclib in HR+ HER2- Early Stage Breast Cancer. <https://clinicaltrials.gov/study/NCT06001762?term=NCT06001762&rank=1#participation-criteria>
5. Johnston, S. et al. Overall survival with abemaciclib in early breast cancer. Annals of Oncology. 2025. DOI: [10.1016/j.annonc.2025.10.005](https://doi.org/10.1016/j.annonc.2025.10.005)
6. Mayer, E. L. et al. TRADE: a phase II trial to assess the tolerability of abemaciclib dose escalation in early-stage HR-positive/HER2-negative breast cancer. Annals of Oncology. 2025. DOI: [10.1016/j.annonc.2025.09.141](https://doi.org/10.1016/j.annonc.2025.09.141)