



NATALEE

TRIAL TITLE

A trial to evaluate efficacy and safety of ribociclib with endocrine therapy as adjuvant treatment in patients with HR+/HER2- early breast cancer (NATALEE)

TRIAL STATUS

Active, not recruiting

TRIAL NUMBER

[NCT03701334](https://clinicaltrials.gov/ct2/show/study/NCT03701334)

TRIAL PHASE

Phase 3

PARTICIPANTS IN THE STUDY

- Adults diagnosed with stage II or stage III ER-positive/HER2-negative breast cancer.
- Participants did not receive a CDK4/6 inhibitor such as palbociclib, ribociclib or abemaciclib prior to enrolling.



BREAST CANCER
breakthroughs

Breast Cancer Breakthroughs FACT SHEET

TRIAL DETAILS:

- 5,101 people with early-stage ER-positive breast cancer were randomized to receive the CDK4/6 inhibitor ribociclib combined with hormone therapy (endocrine therapy) or hormone therapy alone.
- Ribociclib was given as a pill taken daily for three years.
- Researchers are determining if ribociclib combined with hormone therapy prevents or delays breast cancer from coming back compared to hormone therapy alone.

ABOUT EARLY-STAGE ER-POSITIVE BREAST CANCER AND RIBOCICLIB:

- People with early-stage ER-positive breast cancer are typically treated with 5-10 years of hormone therapy after they've completed their surgery.¹
- For more aggressive cases, chemotherapy or the CDK4/6 inhibitor abemaciclib is sometimes given.^{1,2}
- Outcomes are good for people with early-stage ER-positive breast cancer, but everyone is still at risk of recurrence. New treatment options are needed to prevent recurrence.
- Ribociclib is a CDK4/6 inhibitor already approved for metastatic ER-positive breast cancer.³
- Results from the NATALEE trial have shown that ribociclib combined with hormone therapy reduces the risk of breast cancer recurrence by 25% compared to hormone therapy alone.⁴
- The NATALEE trial is ongoing to determine if ribociclib improves overall survival.

REFERENCES:

1. Hormone Therapies: <https://www.komen.org/breast-cancer/treatment/type/hormone-therapy/>
2. Chemotherapy: <https://www.komen.org/breast-cancer/treatment/type/chemotherapy/>
2. CDK4/6 inhibitors for metastatic breast cancer: <https://www.komen.org/breast-cancer/metastatic/metastatic/cdk4-6-inhibitors-for-metastatic-breast-cancer/>
2. Slamon D et al. Ribociclib plus Endocrine Therapy in Early Breast Cancer. *N Engl J Med.* 2024; 390:1080-1091. DOI: 10.1056/NEJMoa2305488

For more information, go to [komen.org/breakthroughs](https://www.komen.org/breakthroughs)