EA1242/RxFINE-Low Study

Do you have breast cancer that was recently removed by surgery?

If so, you may be eligible to participate in this study of potential new treatment approaches.

Testing Whether Hormone Therapy with Ribociclib is as Effective as Chemotherapy Followed by Hormone Therapy with Ribociclib

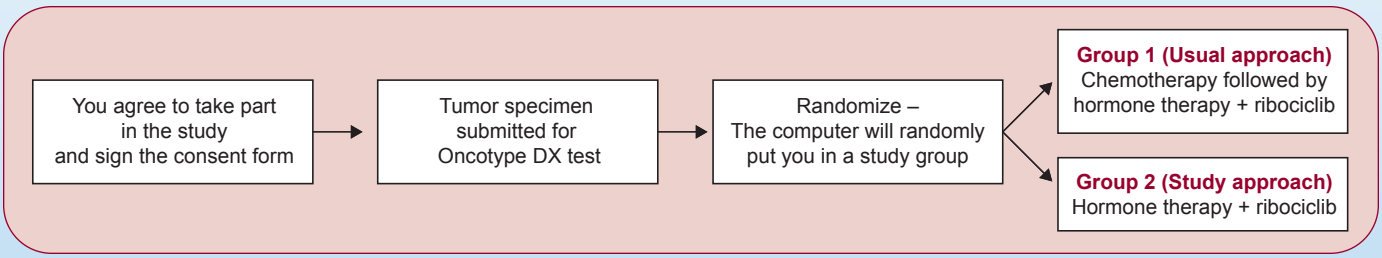
WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches to treating cancer.
- The usual approach (i.e., the standard treatment most patients receive) for breast cancer after surgery is treatment with chemotherapy followed by hormone therapy plus a Food and Drug Administration (FDA)-approved CDK4/6 inhibitor (such as ribociclib). The CDK4/6 inhibitor works together with the hormone therapy to lower the risk of breast cancer returning.
- The purpose of EA1242/RxFINE-Low is to determine if giving hormone therapy and ribociclib without chemotherapy is better or worse than the usual approach that includes chemotherapy. The study is for patients whose breast cancer has a low risk of recurrence (measured by the Oncotype DX Recurrence Score 0–25).

WHAT does this study involve?

If you are eligible for this study and choose to participate:

- A breast tumor specimen from a previous biopsy will be sent to a central lab to determine the Oncotype DX Recurrence Score, which measures the risk of the cancer returning. You will not need to have a new biopsy, and if you had a previous Oncotype DX assay performed, you may be able to use those results for participation.
  - If your tumor specimen's Recurrence Score is 26–100, you will not proceed with the study and your doctor will decide on further treatment.
  - If your Recurrence Score is 0–25, you will be randomized (randomly assigned by a computer) to one of two groups. You will have an equal chance of being in either group.
    - » Treatment in both groups will be given in 28-day cycles. Your specific chemotherapy and hormone therapy will be determined by your doctor.
    - » **Group 1** (about 989 people): Participants will receive the usual treatment of chemotherapy followed by hormone therapy (a pill, taken by mouth [orally] each day) and ribociclib (a pill, taken orally on Days 1–21).
    - » **Group 2** (about 989 people): Participants will receive hormone therapy and ribociclib, both taken as pills orally.
    - » Treatment will be given until your cancer returns, side effects become too severe, or for up to 3 years for ribociclib and at least 5 years for hormone therapy.



  - Cancer treatments can cause side effects. Your study doctor will review possible side effects with you, and you can ask questions about them at any time.
  - For both groups, after you finish study treatment, your doctor will continue to monitor you for up to 10 years from the date you registered for the study. You will be seen by your doctor every 3 months for the first two years, every 6 months for years 3–5, and then yearly for years 5–10.

WHO will take part in this study?

- Approximately 1978 post-menopausal people with breast cancer that has already been removed by surgery will take part in EA1242/RxFINE-Low.
  - The breast cancer must be estrogen receptor (ER)-positive and human epidermal growth factor 2 (HER2)-negative and have a low chance of returning (measured by the Oncotype DX Recurrence Score).
- Participants must not have received prior treatment with a CDK4/6 inhibitor drug, or prior chemotherapy for their breast cancer.
- You can decide to stop taking part in this study at any time, for any reason, even after you have enrolled.

WHAT are the costs of taking part in this study?

- Just as if you were receiving the usual care for your breast cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you will receive as part of EA1242/RxFINE-Low. This includes the costs of tests, exams, procedures, and medications that you get during the study to monitor your safety and prevent and treat side effects.
- You and/or your insurance provider will **not** have to pay for exams, tests, and procedures done for research purposes only, or that are covered by the study. This includes the cost of the Oncotype DX test that will be done to see if you are eligible to participate.
- Talk to your insurance provider to find out what they will pay for. If you are unsure which costs insurance will cover, ask your doctor or nurse for help finding the right person to talk to.
- Taking part in EA1242/RxFINE-Low may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer.
- You will not be paid for taking part in EA1242/RxFINE-Low.

IF you would like more information:

- About the EA1242/RxFINE-Low study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search EA1242, then select the link to the EA1242 page.
    - » If you are seeking information about the locations where this study is available, scroll down the page to Locations and Contacts and click the + sign.
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).
- About clinical trials:
  - General cancer information: visit the NCI website at www.cancer.gov
  - Insurance coverage/paying for cancer treatment: www.cancer.gov/clinicaltrials/learningabout/payingfor
- About ECOG-ACRIN:
  - Visit www.ecog-acrin.org
  - For a list of patient resources and links to patient advocacy groups, visit www.ecog-acrin.org/patients/resources

NCI National Clinical Trials Network

ECOG-ACRIN cancer research group