



Do you have newly diagnosed and untreated HER2-positive breast cancer?

If so, you may be able to take part in this research study of a potential new treatment-monitoring approach.

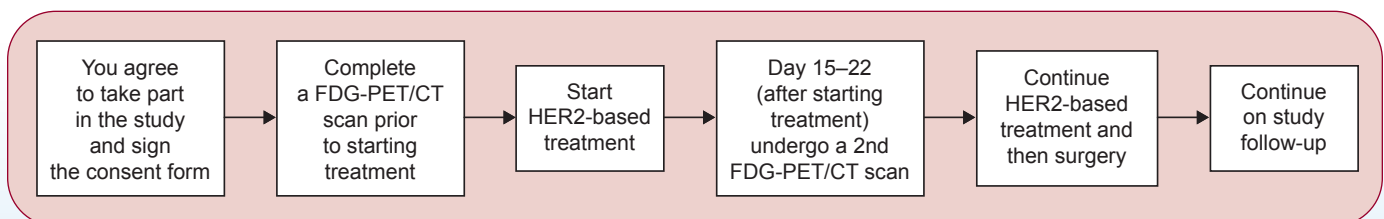
Testing the Role of FDG-PET/CT to Predict Response to Therapy Prior to Surgery for HER2-positive Breast Cancer

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches for treating breast cancer.
- The usual approach to find out how well treatment is working for early-stage breast cancer is to monitor the effect of treatment with physical examination, mammography, ultrasound, or breast MRI before surgery.
- EA1211/DIRECT is being done to investigate if having a different type of imaging test, called a FDG-PET/CT scan, 2–3 weeks after starting your treatment will help predict how your cancer will shrink or respond by the time of surgery. EA1211/DIRECT aims to find out if this approach can be used to make better (more personalized) decisions around treatment for patients with HER2-positive breast cancer.

WHAT does this study involve?

- If you decide to take part in this study, you will have a FDG-PET/CT scan prior to starting chemotherapy and targeted therapy.
- Approximately 2–3 weeks after starting treatment, you will complete a second FDG-PET/CT scan.



- After you finish the two study FDG-PET/CT scans, you will continue your course of treatment, and your doctor will continue to follow you for at least 3 years as part of the study.
- You can decide to stop taking part in the study at any time, even after you have enrolled.

WHO will take part in this study?

- Approximately 235 people with HER2-positive breast cancer will take part in EA1211/DIRECT.
- Participants must not have had any prior treatment for their current breast cancer, including surgery, chemotherapy, hormonal therapy, radiation, or experimental therapy.



WHAT are the costs of taking part in this study?

- Just as you would if you were getting the usual care for breast cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you get as part of this study. Check with your insurance company to find out what they will pay for.
- 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. These include two FDG-PET/CT scans completed after study registration.
 - Note: If you have a FDG-PET/CT scan completed prior to joining this study that can be used, this scan may have already been billed to your insurance and is not reimbursed by this study.

IF you would like to know more

- About the EA1211/DIRECT study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA1211, then select the link to EA1211.
 - » For information about medical facilities where the study is available, scroll down the page to Locations and Contacts.
 - 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: visit 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 <https://ecog-acrin.org/patients/resources>

