ECOG-ACRIN
cancer research group

E4112 Clinical Trial Results Summary

Value of Breast MRI to Treat Patients Diagnosed with Ductal Carcinoma In Situ

What did this trial involve and who was it for?

A total of 368 patients with ductal carcinoma in situ (DCIS) enrolled in E4112. DCIS is an early form of breast cancer that affects the cells that line the milk ducts of the breast.

The usual treatment for DCIS is surgery, followed by radiation therapy to prevent the cancer from coming back (recurring). Currently there is no way of knowing for certain whether DCIS will recur or develop into invasive breast cancer, but most cases do not. Since the risk of recurrence is low, there is concern that some patients might not benefit from radiation treatment. Overtreatment is an important issue because unnecessary treatments can be costly and cause side effects, while not necessarily offering better outcomes for some patients.

In the study, participants who underwent breast surgery for their cancer had tissue collected and genetically tested to identify whether they had low-risk DCIS and could consider safely skipping radiation therapy, or high-risk DCIS and would likely benefit from radiation therapy.

What are the results?

- In 2017, the study's original results were published. Approximately half of the participants had low-risk DCIS and were advised that radiation therapy could be skipped. For participants with high-risk DCIS, radiation therapy was still recommended. Follow-up was planned and conducted to review the long-term treatment outcomes of these patients.
- In 2024, results from the 5-year follow-up were published, and the findings showed that patients with low-risk DCIS did not have a higher risk of recurrence if they did not receive radiation therapy. For patients with high-risk DCIS, the data supported the use of radiation treatment to prevent recurrence.

What do the results mean for patients?

- Patients and their providers can use this information to help guide their breast cancer treatment decision-making.
- For patients with low-risk DCIS (as determined by genetic testing), it may be safe for them to skip radiation therapy.
- For patients with high-risk DCIS, radiation therapy is still recommended.

For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: https://clinicaltrials.gov/study/NCT02352883
- ECOG-ACRIN Website: https://tinyurl.com/E4112results
- Journal of Clinical Oncology (original publication; 2017): https://ascopubs.org/doi/10.1200/JCO.2017.35.15_suppl.534
- Dr. Khan on E4112's 5-year follow-up results in The ASCO Post: https://tinyurl.com/E4112ASCOPost

This summary lists what is known about this research study as of November 2024.
New information may be available.

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

About ECOG-ACRIN

This trial was led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN). ECOG-ACRIN is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN is a component of the National Cancer Institute's National Clinical Trials Network. Learn more at www.ecog-acrin.org.

To all the patients that participated in this trial, thank you. Without the involvement of patients like you, this research would not have been conducted.