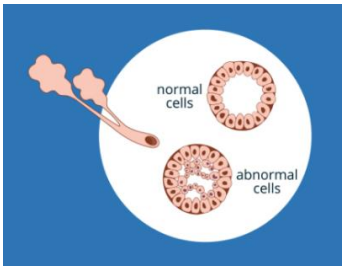
COMET
A Study for Low Risk DCIS
Expanding Knowledge and Options

News about Low-Risk Ductal Carcinoma In Situ (DCIS)

Ductal Carcinoma In Situ (DCIS) is a precancerous breast condition that is found mostly on mammograms due to calcium deposits. More than 50,000 women are diagnosed with DCIS in the United States (U.S.) each year. DCIS is very rare in men, but it can happen.

What is DCIS?



DCIS refers to abnormal cells found inside a milk duct. Research shows that most women with DCIS will not get a future invasive breast cancer. Even so, guidelines currently recommend that DCIS be treated the same way as invasive breast cancer. Currently, almost all U.S. patients (98%) receive surgery to remove DCIS, and almost 5 in 10 (50%) also get radiation therapy after surgery.

There are different types of DCIS. Some are considered low-risk and others are higher risk. Low-risk DCIS is labeled Grade 1 or 2 on a biopsy or pathology report. Low-risk DCIS is also Hormone Receptor Positive (DCIS cells respond to hormones). About 5 in 10 (50%) of all patients diagnosed with DCIS have low-risk DCIS.

What is the COMET Study about?

The **Comparing an Operation to Monitoring with or without Endocrine Therapy (COMET) study** is the first large, randomized clinical trial to compare surgery to Active Monitoring as a treatment for women with low-risk DCIS. This means the study has balanced groups that help compare rates of invasive breast cancer between Active Monitoring and Surgery.

Active Monitoring can be done instead of surgery and radiotherapy. Active Monitoring includes regular mammograms to check for early changes after being diagnosed with low-risk DCIS. If changes happen, surgery can then be done if necessary.

The study also:

- Measured differences in quality of life and levels of anxiety, depression, worries, and symptoms related to DCIS treatment, no matter what treatment they received.
- Collected samples of DCIS and images to study more ways to lower DCIS risk in the future.

Why was the COMET Study done?

Past studies suggest that most women with low-risk DCIS may not get a further DCIS or invasive breast cancer, even if DCIS is not treated with surgery or radiotherapy. The problem is that no studies compared surgery to Active Monitoring for women with low-risk DCIS to find out about the safety of Active Monitoring. This has created hesitation and uncertainty about whether all women with DCIS need surgery.

The goal of the COMET Study is to answer this important question for women with low-risk DCIS. With better evidence, breast cancer doctors and researchers can be more confident in offering Active Monitoring for low-risk DCIS rather than having surgery right away.

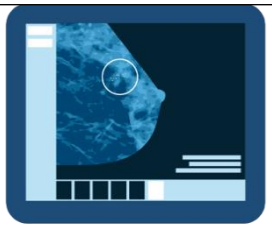
How was the COMET study done?

Half assigned to surgery



Almost 1,000 women with low-risk DCIS joined the study from 2017 to 2023 in 100 U.S. locations. It was the first U.S. randomized clinical trial to look at different strategies for low-risk DCIS. Neither doctors nor participants chose their group. This was important to make sure both groups were balanced. Some women refused their assigned care but were still followed. Many women in both groups chose endocrine therapy which blocks estrogen and progesterone hormones.

Half assigned to Active Monitoring



Information was also collected from COMET participants throughout the study about how they felt.

The study was funded by Patient-Centered Outcomes Research Institute, Breast Cancer Research Foundation, and Rising Tide Foundation. Alliance Foundation Trials sponsored the study.

Thanks to the women who participated in this study!

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What are the results of this study?

Results of the COMET Study help doctors and patients better understand the risks and benefits of both Active Monitoring and surgery. This helps provide safe recommendations and options for patients with low-risk DCIS in the future.

The COMET Study found that women with low-risk DCIS who get Active Monitoring are no more likely to develop invasive breast cancer after 2 years than women who get surgery. COMET participants are being followed for several more years to find out if these results will last or change.



At 2 years of follow up, the COMET Study showed that:

- The rate of invasive cancer in women in the Surgery group was about 6 in 100 women (5.9%).
- The rate of invasive cancer in women in the Active Monitoring group was about 4 in 100 women (4.2%).
- There were no differences in how participants felt about their health, no matter which group they were in.

"The women in the study told us in surveys how they felt over time," said Dr. Partridge, who led this part of the study. "Fortunately, the overall quality of life, anxiety, depression, worries, and symptoms were comparable regardless of the treatment received for up to 2 years of follow-up."

What do the results mean for people with Low-Risk DCIS?

"These early results are exciting for patients with low-risk DCIS, and we are waiting for long-term follow-up on these participants." Dr. Hwang, the study leader said. "If these results hold up over time, women with low-risk DCIS may consider the option of avoiding invasive treatments for Active Monitoring. That would be a complete change in how we care for these patients and think about low-risk DCIS."

The COMET Patient Leadership Team notes, "The results support patients with low-risk DCIS to take the time they need (up to 2 years after diagnosis) to make a treatment decision that most closely aligns with their personal preferences."

Some important limits about this study include:

- Longer follow-up is necessary to confirm these results.
- Over half of COMET participants received hormone therapy which has lowered rates of invasive breast cancer.
- The slightly higher rate of invasive breast cancer in the surgery arm might be based on "upstaging." This means that invasive breast cancer was found at the time of surgery.

What are the next steps?

COMET Study results were shared at the San Antonio Breast Cancer Symposium in December 2024. The Study Team, which includes patient advocates, continues to follow COMET participants to track their progress and will report on 5-year results in the future.

Where can I find out more?

The studies were published in JAMA and JAMA Oncology in December 2024.

Hwang ES et al. "*Active Monitoring With or Without Endocrine Therapy for Low-Risk DCIS: The COMET Randomized Clinical Trial.*" JAMA 2024.

Partridge AH et al. "*Patient Reported Outcomes for Low-Risk Ductal Carcinoma In Situ: Findings From the COMET Randomized Clinical Trial.*" JAMA Oncology 2024.

For more DCIS information, check out DCISoptions.org

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