#PS3-03-08: Initial results from RECAST DCIS: Multicenter platform trial testing active surveillance and novel endocrine therapy agents for DCIS management

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Abstract

- Ductal Carcinoma In Situ (DCIS) is a **heterogeneous, non-invasive breast condition** with variable progression risk; many patients may be overtreated under the current standard of care
- RECAST is a Phase II adaptive platform trial evaluating whether neoadjuvant endocrine therapy can identify candidates for **long-term active surveillance (AS)**.
- Early findings show **excellent tolerability, steady accrual,** and a high proportion of patients continuing AS.

Background

- DCIS involves malignant epithelial proliferation confined to the ducts but does not always progress to invasive cancer (Figure 1).

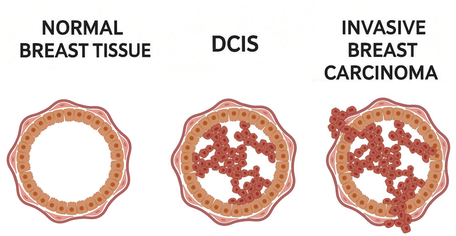


Figure 1: Normal breast tissue compared to DCIS and breast cancer

- Standard treatment (surgery ± endocrine therapy ± radiation) may overtreat a substantial number of patients.
- Endocrine therapy in the neoadjuvant setting may help 1) evaluate endocrine responsiveness; 2) identify progression risk; 3) support shared decision-making and reduce overtreatment.

Clinical Trial Design

Serial MRIs are conducted (baseline, three, and six months) and determines patient suitability for AS or surgery (Figure 2)

- Eligibility: Hormone receptor–positive DCIS (all grades).
- Randomization to one of the endocrine agents (Figure 3)



Endocrine Agents:

1. Standard endocrine therapy (Tamoxifen/AI)
2. Elacestrant
3. HAV-088
4. z-Endoxifen

Figure 3: Randomization Process

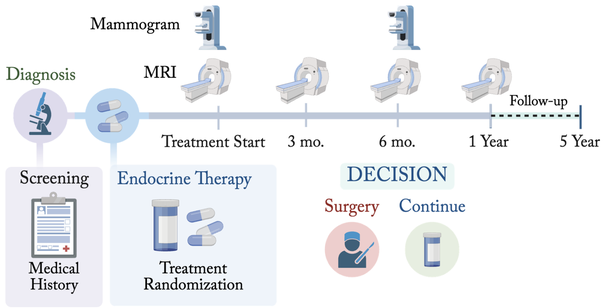


Figure 2: RECAST study schedule

- Evaluation of DCIS lesion response and background parenchymal enhancement (BPE).
- Imaging response determines whether patients continue AS or proceed to surgery.

Results



Figure 4: RECAST active national study sites

Acknowledgement:
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- 50+ enrolled to date - target accrual: 400

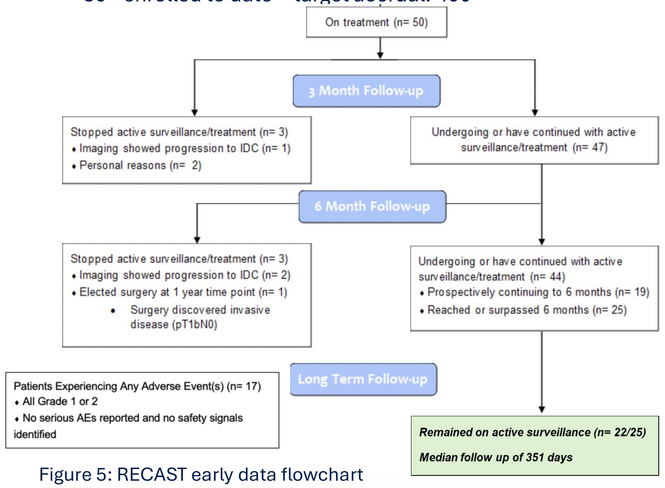


Figure 5: RECAST early data flowchart

Discussion

Early RECAST Findings: Window of Opportunity for Personalized DCIS Care

Identifies Candidates for Long-Term Active Surveillance (AS)
Early endocrine response helps distinguish who may safely defer surgery

Reduces Overtreatment
Targets endocrine therapy to those who benefit; avoids unnecessary procedures

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Improves Patient Experience & Quality of Life
Avoids surgical morbidity when possible
Provides more time for reflection and informed choices

Patient-Centered "Window of Opportunity" Model
Empowers patients to:
- Assess real-time response to endocrine therapy
- Evaluate medication tolerability

Make shared, values-aligned decisions with their clinicians

Figure 6: Early data reveals meaningful information

- The patient-centered "window of opportunity" model, which empowers individuals to assess both response and medication tolerability, improves shared decision-making (Figure 6).

Future Directions

- Refine predictive criteria by integrating MRI response with molecular and endocrine biomarkers to better identify candidates for long-term AS.
- Enhance risk stratification using imaging–genomic correlations to personalize treatment pathways.
- Evaluate long-term outcomes, including durability of AS, recurrence patterns, and rate of invasive progression among responders.
- Assess extended endocrine therapy to determine its sustained impact on risk reduction and medication tolerability