SURVIVE Study

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Reevaluating follow-up in early breast cancer, guided by liquid biopsy: the SURVIVE study (standard surveillance versus intensive surveillance in early breast cancer)

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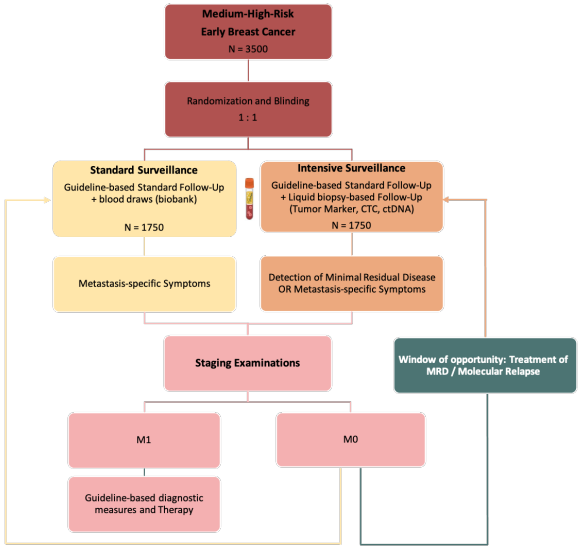
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Background

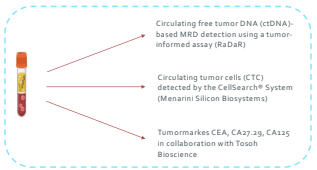
Current guidelines limit routine follow-up in early breast cancer (EBC) patients to clinical exams and breast imaging, discouraging screening for distant recurrence in asymptomatic patients. These recommendations are based on large studies conducted in the 1980s, which showed no survival benefit from intensified surveillance, even though a lead time could be established even over 30 years ago (Del Turco et al. 1994; Liberati et al. 1995). Given recent advances in both therapy and diagnostics, a re-evaluation of surveillance strategies for EBC patients to detect relapse at a pre-symptomatic stage is urgently needed.

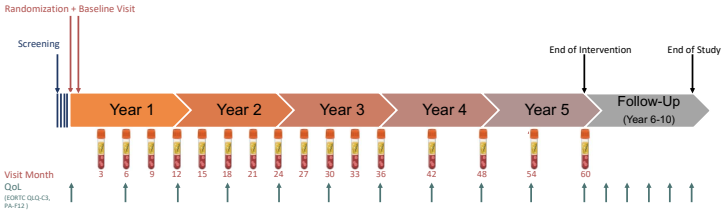
Trial design

Funded by the German Ministry of Research, Technology and Space (BMFTR), the SURVIVE study is a prospective multicenter randomized controlled trial, investigating the potential survival benefit of a liquid biopsy-guided follow-up in intermediate- to high-risk EBC patients (all subtypes).



Methods





Key eligibility criteria

Histologically confirmed primary invasive intermediate-/ high-risk EBC, defined as:

- indication for (neo-)adjuvant chemotherapy
- and/or large tumor size (> 50 mm)
- and/or positive lymphnodes (≥ pN1mi)
- and/or high grade (≥ G3)

Complete resection (R0) and primary tumor tissue available

Completion of primary anti-tumor therapy (surgery, adjuvant chemo- or radiotherapy) ≤ 24 months before study enrolment (≤ 60 months for luminal carcinoma)

Endpoints

Two Co-Primary-Endpoints will be investigated:

1. Overall Survival (OS)
2. Overall Lead Time

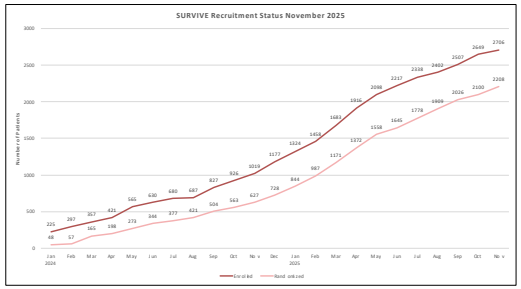
Secondary Endpoints include invasive disease-free survival, distant disease-free survival, distant recurrence free survival, breast cancer-specific survival and quality of life.

Conclusion

The SURVIVE study is a long-awaited trial investigating whether intensified, liquid biopsy-guided follow-up in early breast cancer enables earlier detection of recurrence and improves overall survival. If successful, the results will lead to a paradigm shift in current follow-up care of intermediate- to high-risk early breast cancer survivors and may pave the way for earlier treatment options at the point of minimal residual disease (MRD) or molecular relapse.

Current status

- 3131 of 3500 patients enrolled since 12/2022
- 98 study centers recruiting across Germany
- Last patient in (LPI) expected 09/2026
- First results expected 2030



Study Homepage

clinicaltrials.gov

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