

Targeted Intraoperative Radiotherapy Boost Quality Registry (TARGIT BQR)

Statistical Analysis Procedures – 09. December 2025

(NCT01440010)

PI: Elena, Sperk; MD

Oncological Outcome

Outcome variables were local recurrence, ipsilateral breast carcinoma, contralateral breast carcinoma, local lymph node metastasis and distant metastasis. Kaplan-Meier estimates were done to calculate cumulative rates for disease-free survival, local recurrence rate, local recurrence-free survival, metastasis-free survival and overall survival. For all Kaplan-Meier estimates, death was also counted as an event and not censored, except for local recurrence rate where only recurrences were counted as an event. For disease-free survival any event (death, local recurrence, metastasis, ipsilateral breast carcinoma, contralateral breast carcinoma, local lymph node recurrence) was included whatever occurred first. Eight patients had bilateral breast cancer and were counted once in case of an event of metastasis or death. The statistical analysis was performed for the endpoints of the oncological outcome in an intention-to-treat-setting using SPSS, Version 27.

Toxicity

For cumulative toxicity rates grade 2 fibrosis, breast edema, lymphedema, hyperpigmentation, retraction, and pain were documented if they occurred at least 3 times during the follow-up period. Teleangiectasia and ulceration, irrespective of their severity, were recorded as single occurrences. Data on acute and long-term toxicity were recorded. Simple frequencies, relative and absolute values, and cumulative rates were calculated. Cumulative rates were calculated based on the Kaplan-Meier method (SAS, release 9.3 and SPSS, Version 27). This is an intention-to-treat-analysis of the whole cohort. All data were collected at the study center in Mannheim. The registry closed recruitment in December 2020.