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# Surveillance AFter Extremity Tumor surgerY (SAFETY): Results of the Pilot International Randomized Controlled Trial


## Authors

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## Background

Following surgical resection of a high-risk extremity soft-tissue sarcoma (STS), between 40 and 50% of all patients will develop a local or distant recurrence. Earlier detection of a less advanced disease recurrence may prolong survival; therefore, intensive post-operative surveillance, especially of the lungs, is routine practice. However, the adverse effects of intensive surveillance must also be considered, including healthcare costs, false-positive results, the financial/emotional burden on patients, and unnecessary radiation exposure.

## Methods

The Surveillance AFter Extremity Tumor surgerY (SAFETY) trial is an international multi-center randomized controlled trial (RCT) that addresses the following question: *Does the frequency and mode of surveillance affect patient survival following extremity soft-tissue sarcoma (STS) surgery?* Patients are randomized into one of four surveillance groups for the first two years of follow-up: (1) CXR every three months, (2) CT every three months, (3) CXR every six months, or (4) CT every six months. The primary outcome is overall survival at five years. The secondary outcomes include quality of life and healthcare costs.

## Results

At the time of abstract submission, 127 patients have been randomized across 23 enrolling clinical sites in eight countries (Argentina, Australia, Austria, Brazil, Canada, Italy, the Netherlands, and the USA). An additional 13 clinical sites are in the active start-up phase. Patient interest in the trial has matched or exceeded expectations and pilot study metrics (data quality, protocol adherence, and participant retention) support the feasibility of transitioning to the definitive study.

## Conclusion

STS patient surveillance has been identified by consensus as a top research priority in the field. The SAFETY investigators have successfully demonstrated the ability to coordinate international RCTs through the PARITY trial and continue to do so in the SAFETY trial. Further expansion of the SAFETY international collaborative network will be critical for the recruitment of the SAFETY target sample size, and MSTS members are encouraged to visit the study website at www.SAFETYrct.com to register as an investigator.