



SAFETY

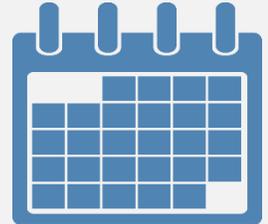
Surveillance After Extremity Tumor Surgery

February 2020 ■ Edition 2

Welcome to the second edition of the **Surveillance AFter Extremity Tumor surgerY (SAFETY)** Trial Newsletter!

STUDY RATIONALE AND IMPACT

Following treatment for a primary extremity soft-tissue sarcoma (STS), patients remain at risk for the development of local and systemic / distant disease recurrence. Metastasis (distant recurrence) to the lung is the most frequent single location of disease recurrence in STS patients, occurring in almost half of all patients. Therefore, careful post-operative surveillance is an integral element of patient care. However, the detection of metastases does not necessarily affect long-term survival and may negatively impact quality of life. Surveillance strategies have been identified as the top research priority in the extremity sarcoma field. The SAFETY trial will provide the necessary evidence to develop evidence-based surveillance guidelines and is poised to have a significant impact on post-operative care and outcomes of extremity STS patients.



STUDY OVERVIEW

The overarching objective of this trial is to answer the following research question:

Does the frequency and mode of surveillance affect patient survival following extremity STS surgery?

To do so, we will compare two surveillance frequencies (every 3 months vs. every 6 months) and two imaging modalities (chest CT scans vs. chest radiographs). Patients will be randomized to one of four treatment groups:

- Clinical assessment and **chest CT** scan every **3 months** for 2 years;
- Clinical assessment and **chest CT** scan every **6 months** for 2 years;
- Clinical assessment and **chest radiograph** every **3 months** for 2 years; or
- Clinical assessment and **chest radiograph** every **6 months** for 2 years.

Upon completion of the 2-year ‘intervention phase’, study participants will continue to be followed in the study every 6 months for another 3 years. The primary outcome is overall survival at 5 years post-randomization.

RECRUITMENT UPDATE

We are pleased to report that as of 3 February 2020, **2** participants have been enrolled in the SAFETY trial.

Site	Country	Enrolled Since Last Update	Enrolled to Date	Pilot Phase Enrolment Target
Juravinski Hospital and Cancer Centre	Canada	2	2	1%

SITE INITIATION UPDATE

The following sites are actively working to complete the required study initiation activities before participant recruitment commences.

Site	Country	Ethics Approval Status	Site Agreement Status	Site Training Status
McGill University Medical Centre	Canada	In Progress	In Progress	N / A
Hôpital Maisonneuve-Rosemont	Canada	In Progress	In Progress	N / A
Holden Comprehensive Cancer Centre	USA	In Progress	In Progress	N / A
Oregon Health & Science University Hospital	USA	In Progress	In Progress	N / A
The Cleveland Clinic	USA	In Progress	In Progress	N / A
University of California Davis Medical Center	USA	In Progress	In Progress	N / A
Yale New Haven Hospital	USA	In Progress	In Progress	N / A
Leiden University Medical Center	Netherlands	In Progress	In Progress	N / A
Hospital Vall d’Hebron	Spain	In Progress	In Progress	N / A

SAVE THE DATES!

COLLABORATION DINNER IN GRAZ!

To celebrate the ongoing success of our collaborative research network, the SAFETY team will be hosting a reception while attending the European Musculo-Skeletal Oncology Society (EMSOS) Annual Meeting in Graz, Austria. The dinner will likely follow the reception dinner on 13 May 2020. Please stay tuned for further details.

We look forward to dining with you in Graz!



The recruitment target for the pilot phase of the SAFETY trial is **200** participants. To reach this target, the Methods Centre is actively seeking high volume sites with research support to join the pilot phase of the trial. If you know of any individuals who may be interested in participating in this collaborative study, please inform the **Methods Centre**.

SUCCESS BULLETIN!

FIRST SAFETY PARTICIPANTS ENROLLED!

We are happy to report that the first two patients approached to participate in the study both consented! They were successfully randomized into the study on 19 November 2019 and 14 January 2020, respectively. We look forward to more sites opening to recruitment soon!

FUNDING UPDATE

At present, we have received the following funding to conduct the Canadian pilot study:

- Hamilton Academic Health Sciences Organization (HAHSO) Innovation Fund; and
- Canadian Cancer Society Research Institute (CCSRI) Innovation Grant.

We are also in the process of applying for a Canadian Institutes of Health Research (CIHR) Operating Grant to support the international expansion of the definitive trial.



Canadian Cancer Society
Société canadienne du cancer



SAFETY WEBSITE

The SAFETY trial website is now live, which will serve as primary mode of communication for important information from the Methods Centre. Please visit www.SAFETYrct.com to complete the SAFETY Physician Trial Application or to access the study documents.

SAFETY PROTOCOL PUBLISHED!

The SAFETY trial protocol has published in *BMJ Open*. The full article can be accessed online at: <https://bmjopen.bmj.com/content/9/9/e029054.info>.



CLINICAL TRIAL REGISTRATION

The SAFETY trial has been registered on ClinicalTrials.gov (NCT03944798).

METHODS CENTRE CONTACTS

If you have questions about any aspect of the study, do not hesitate to contact:

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